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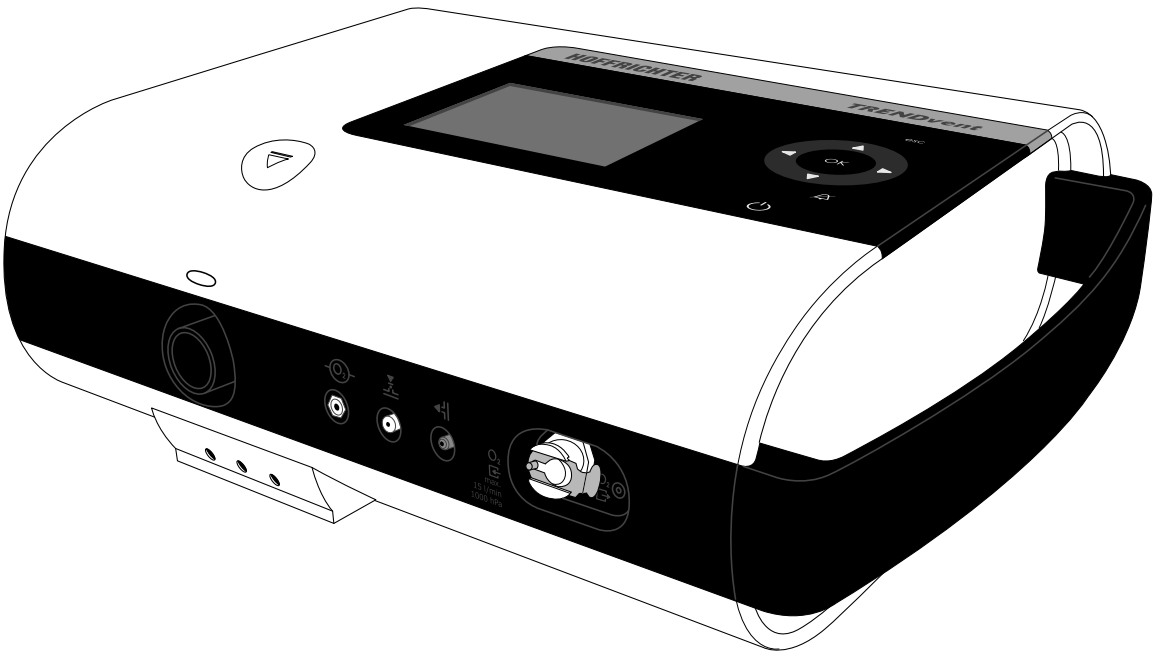
Quality makes the Difference

TRENDvent



User's manual for patients
Ventilator

SERIAL NUMBER

Every HOFFRICHTER GmbH device is supplied with a serial number for traceability purposes.

Please enter your device's serial number here. You will find the serial number on the rating plate on the bottom of the device.

Serial number: .....

Please always quote the serial number for all queries and complaints.

CONFORMITY

The device complies with the requirements of Directive 93/42/EEC.

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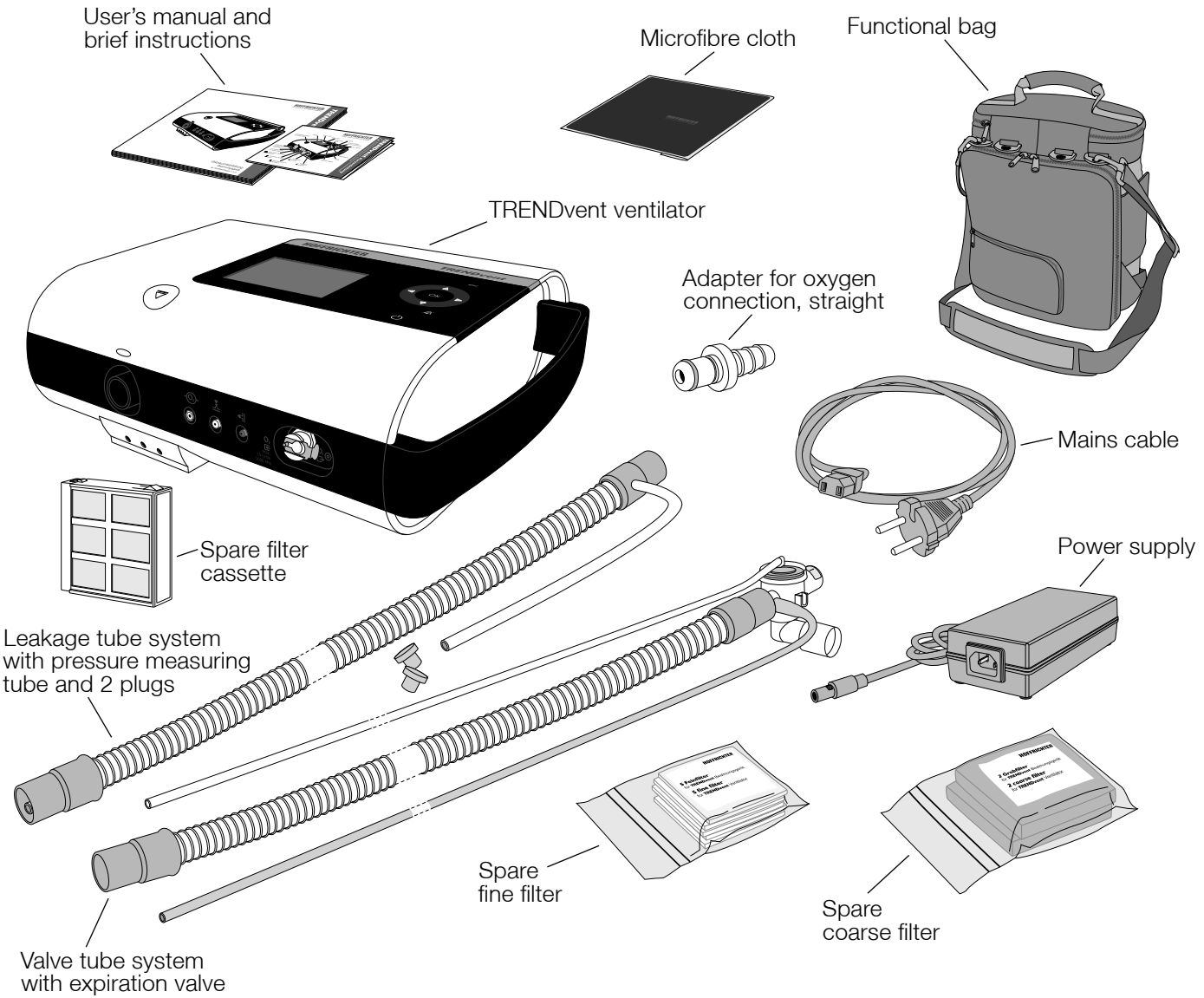
SCOPE OF DELIVERY



GENERAL

INFORMATION ON USER'S MANUAL

Read this user's manual through carefully before using the ventilator for the first time.

Follow the safety and cleaning instructions in particular.

Keep the manual in a safe place close to the device so that you can refer to it immediately if necessary.

SYMBOLS ON THE RATING PLATE

Observe the warning and safety instructions in the user's manual.

BF application part

Protection class II (protective insulation)

IPX1 Drip-proof device

CE conformity declaration

Manufacturer

Do not dispose of the device with the household waste. Please contact the relevant customer services department to find out how to dispose of the device properly.

SYMBOLS USED IN THIS USER'S MANUAL

Important information is denoted by symbols in this user's manual. Be sure to follow these instructions in order to avoid accidents, personal injury and material damage.

In addition, the local accident prevention regulations and general safety regulations in force in the area of use must be observed.

This symbol denotes general safety instructions. Follow these instructions to avoid accidents, personal injury or material damage.

⚠ DANGER

This symbol denotes hazardous situations that lead to serious injuries or death.

⚠WARNING

This symbol denotes hazardous situations that may lead to serious injuries or death.

⚠CAUTION

This symbol denotes hazardous situations that may lead to moderately severe injuries.

NOTICE

This symbol denotes situations that may lead to material damage or damage to the device.

IMPORTANT

This symbol denotes information, tips and instructions for the efficient, error-free use of the device.

SAFETY INFORMATION

GENERAL SAFETY INSTRUCTIONS

- Only qualified, trained, specialist medical staff under the supervision of a physician may make adjustments to the ventilator. The device must only be used by persons who have fully read and understood this user's manual before commissioning and have familiarized themselves with the device. Disregarding these instructions can lead to life-threatening situations for the patient.
- In cases of emergency, an alternative ventilation option, such as a second ventilator or an emergency ventilation bag, must be available at all times and be usable by the attending person.
- The device must only be used on the responsibility and prescription of the physician.
- The device must only be used on patients whose clinical picture requires its application.
- Please take the utmost care to ensure that the patient remains connected to the tubing system during ventilation.
- The device must not be used with flammable anesthetics or ambient air that contains explosive gases. This may cause fires or explosions.
- Before being used again on another patient, all parts that come into contact with respiratory gas must be hygienically prepared (see page 82).
- The directions given in this user's manual and the applicable regulations of the hospital or nursing home must be adhered to when hygienically preparing and cleaning the device.

- We recommend the use of the tube systems tested and approved for use by the manufacturer. Using other tube systems may lead to differing results.
- When a valve tube system and a nasal or full-face mask is used for non-invasive ventilation, this mask must not contain an expiration opening.
- Always ensure that when using a leakage tube system, the small aperture in the mask or the connecting piece between the mask and the tube is clear so that the CO_2-laden exhaled air can escape.
- When using a valve tube system, the controlled expiration valve must not meet any resistance during exhalation and must enable quick ventilation of the ventilation tube system.
- Please observe the expiration date when using a bacterial filter.
- In order to ensure patient safety, the device must be operated in such a way that all adjustable alarms are activated and adjusted to the patient.
- Acoustic alarms must not be ignored. They indicate conditions that require an immediate reaction.
- In case of extraordinary efforts on the patient's part, there is a risk of hyperventilation in all ventilation modes with inspiration triggering.
- The device's housing provides only minimal protection against water penetration.
- The device must not be steam-sterilized in an autoclave.

- Filters and other parts that are connected to the device must be regularly replaced. Dispose of the replaced parts according to the regulations for used medical material and/or the local environmental protection rules.
- A device that is not functioning properly may endanger the patient or operator. If the device does not start properly or if the self-tests, automatically performed on system start, fail to be completed successfully, the device must not continue to be used. Please notify the service agency in such a case.
- The connection of accessories or other components to the respiratory system of the ventilator can lead to increased expiratory pressure at the patient connection opening.
- Please ensure that the total resistance of the ventilation system does not exceed 6 hPa with a flow of 60 l/min for adults and 30 l/min for children.
- Any modification to the device poses a threat to its serviceability and is not permitted.
- Masks may only be used on the prescription of a physician and after training by qualified medical staff. The intake of medicines and possible contraindications and side effects associated with the use of the prescribed mask should be clarified.
- When the device is used in mobile operation, the power must supplied by AKKUPACK uni or AKKUPACK CARAT.
- Please note the operating, transport and storage conditions.

ELECTRICAL SAFETY

- Do not use any electrically conductive or electrostatically chargeable patient tubes.
- The device must never be put near other devices or equipment such as defibrillators, diathermy units, mobile phones, microwaves, remote controlled toys, etc. Electromagnetic fields that exceed 10 V/m may adversely affect the operation of the ventilator.
- Only the power supply cable supplied may be used for operating the device.
- The use of accessories or power supplies not approved for the ventilator may lead to increased emission of electromagnetic radiation or reduced resistance to interference.
- During certain examinations or treatments, mutual interference between the ventilator and other medical devices may occur. Observe the information regarding electromagnetic compatibility and monitor the devices with regard to error-free and proper operation.
- Do not reach for the device under any circumstances should it fall into water.
- Do not try to open the device. Maintenance and repairs may only be performed by personnel authorized by HOFFRICHTER GmbH.

INSTALLATION REQUIREMENTS AND TRANSPORT

- For operation, the device must be placed on a safe, level base. The air inlet at the rear of the device, as well as all ventilation slots, must not be blocked.
- The display and all operating and display elements must not be covered and must be visible at all times.
- No objects must be placed on the device.
- Place the device in such a way that the mains plug is easily accessible so that it can be unplugged quickly in the event of a hazard.
- The device must not be exposed to direct sunlight.
- The system must never be stored or transported at ambient temperatures under - 10 °C and over + 50 °C.
- Due to electromagnetic interference, the ventilator must not be set up in the immediate vicinity of other devices. If this is unavoidable, the ventilator must be monitored with respect to error-free and proper operation.

INSTRUCTIONS BEFORE COMMISSIONING

- A functional test must be carried out each time before commissioning (see page 88).
- At temperatures below - 5 °C and over + 50 °C, the function of the device may be impaired.
- Do not use the device if the housing or the cable of the device or the power supply are damaged.
- The ventilation system, including all accessories such as humidifiers, bacterial filters etc., must be checked for leaks before ventilation. Leaks may lead to personal injury or inadequate therapy.
- Clean and check all accessories regularly, particularly the tube/mask system. When doing this, observe the manufacturer's safety and cleaning instructions.

USING OXYGEN

- Oxygen may only be supplied on the prescription of a physician. An excessive oxygen supply can lead to serious complications for the patient.
- Oxygen supports combustion. Therefore, observe the fire protection regulations applicable for using oxygen. Ensure that the oxygen fittings, as well as all ports and surfaces near the oxygen lines are free of grease. Do not smoke and do not handle naked flames. When using oxygen, an increased oxygen concentration in the ambient air can occur.
- If the patient is supplied with oxygen via the device, the FiO_2 should be measured.
- Please be sure to observe the user's manual of the manufacturer or distributor from whom you obtain the oxygen.
- The FiO_2 can be measured using the oxygen sensor optionally available from HOFFRICHTER. We recommend the exclusive use of these sensors (see "Accessories" on page 92.)
- The oxygen sensor contains a caustic liquid. Avoid skin or eye contact if there is a sensor leak!
- Please observe the expiration date when using an oxygen sensor (see page 54).
- The oxygen supplied must not exceed a pressure of 1000 hPa and a flow of 15 l/min. The oxygen must be dosed using an external flow meter.

- When supplying oxygen, it should be ensured that only dry gas (O_2) is used. Increased residual moisture may lead to device defects. If necessary, a humidifier can be connected between the air outlet of the device and the patient.
- The connection between the O_2 connection and external O_2 source must be absolutely airtight. Otherwise, leakage losses may occur during ventilation.
- The oxygen supply should be stopped before the ventilation is interrupted. We further recommend that, after stopping the ventilation, the device is allowed to run for several respiratory cycles without an oxygen supply.
- In the event of an oxygen leak, the oxygen supply should be closed off immediately. The room must immediately be ventilated. At the same time, any sparks, fire or potential sources of fire in the vicinity of the device must be avoided.

SAFETY-RELATED TEST

- In order to ensure the operating safety of the device, a safety-related test or maintenance must be carried out at the prescribed intervals.

INTENDED USE

⚠WARNING
The use of the device contrary to its intended use can lead to a hazard to the health of the patient.

The device is used for pressure-controlled respiratory support, as well as the ventilation of patients who are not completely dependent on mechanical ventilation. It is suitable for adults and children from a tidal volume of 50 ml onwards, and can be used both in the home or clinic.

The ventilation can be invasive (e.g. via a tracheotomy) as well as non-invasive (via a mask). The device fulfils the technical requirements to be operated with a leakage tube system or a valve tube system with expiration valve, as required. For ventilation with increased oxygen concentrations, the device can be connected to a low-pressure gas source. Furthermore, it is also possible to combine the device with the AquaTREND uni plug-in humidifier or, during invasive ventilation, with an external humidifier.

CONTRAINDICATIONS

⚠WARNING
Respiratory therapy may be contraindicated for certain pre-existing conditions.

The following conditions may be a contraindication for non-invasive ventilation:

- Severe cardiac arrhythmia
- Severe hypotension
- Severe epistaxis
- Pneumothorax or pneumomediastinum
- Pneumoencephalus
- Cranial trauma
- Status after cranial or brain surgery
- Acute inflammation of the paranasal sinuses, middle ear infection or a perforated ear drum
- Aspiration hazard

In individual cases, the attending physician must decide on the therapy.

SIDE EFFECTS

The following undesired side effects may occur in connection with artificial respiration:

Invasive ventilation:

- Complications due to tube / tracheal cannula

Mask ventilation:

- Pressure points and skin defects in the face
- Eye irritation due to leaks
- Gastric inflation
- Aspiration
- Sinusitis
- Nose bleeds

General complications of mechanical ventilation:

- Pulmonary barotrauma / volutrauma caused by ventilation
- Ventilator-associated pneumonia
- Effects on the cardio-vascular system

HOW THE DEVICE WORKS

IMPORTANT COMPONENTS

The TRENDvent ventilator comprises the following components:

- Blower
- DC / Communication
- Sensors / valves (compressed air distribution)
- Power supply
- Controller (control and operating unit)
- Interfaces

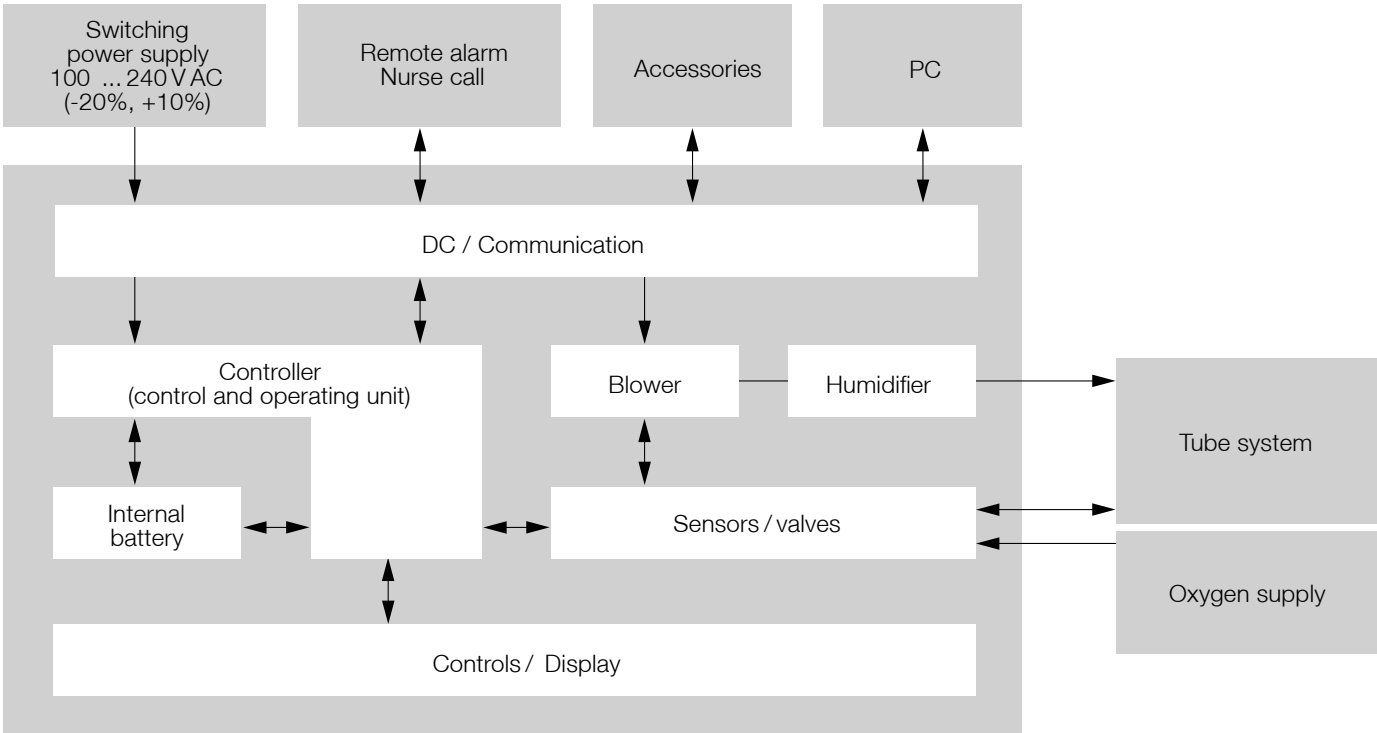


Fig. 1: Block diagram of entire device

Blower

The blower provides a maximum pressure of 40 hPa at a flow of 200 l/min. On the air inlet side there is an air filter cassette with a coarse and a fine filter.

Power supply

The device is supplied with power via an AC/DC switching power supply or the internal battery. The device can also be provided with an external power supply using the AKKUPACK uni or AKKUPACK CARAT. Ask your specialist dealer about this.

Distribution of air in the device

For the distribution of the compressed air, the device is composed of the following units:

- Blower (40 hPa at 200 l/min)
- Air outlet (standardized tube connector [M22]) with flow element and proportional valve
- Non-return valve
- Humidifier (optional)
- Oxygen block including 3/2 directional valve and self-locking connection
- Pressure measuring tube connection (∅ = 3.5 mm)
- Control pressure tube connection (∅ = 4.5 mm)
- Connection for oxygen sensor (jack 2.5 mm)

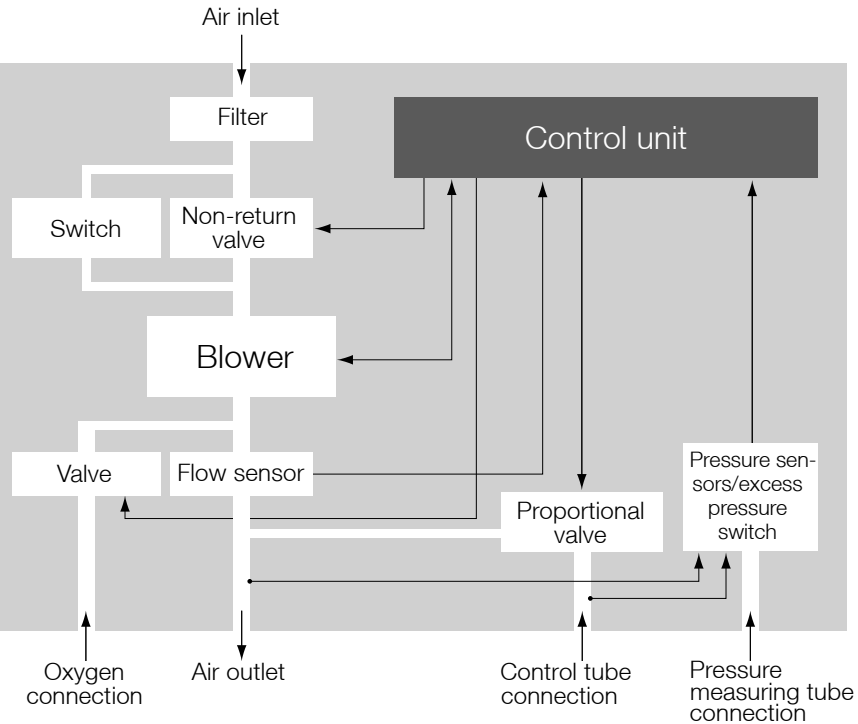


Fig. 2: Block diagram of compressed air distribution

Interfaces

The device has an USB interface for connection to a PC. This interface enables the PC software VENTcontrol to be used to communicate with the device and software updates can be carried out. There is also a connection for the nurse call or a remote alarm box. For servicing, the device has an RS232 interface.

HOW THE DEVICE WORKS

The function of the TRENDvent ventilator is based on a control mechanism, which adjusts the power of the blower to the air output required for therapy in a closed loop. The blower power is controlled by the signal of the respiratory pressure and the signal of the inspiration flow.

Starting the device (initialization)

When the device is started, the parameters are read from the memory (EEPROM) and checked for validity. The pressure, the flow sensor and the acoustic alarm are also tested. In the event of an error, the error detection is saved and shown on the screen.
The calibration data is loaded from the EEPROM and tested for validity. If an oxygen sensor is connected, it is calibrated against the ambient air.

Parameter measurement

The device's analog measurements are read in and analyzed. Target values are calculated on the basis of the set parameters and/or ventilation modes. Then the target values are transferred to the motor control via a digital-to-analog converter (DAC).
The proximal pressure, the valve-control pressure and inspiration flow are measured. This data is used to calculate the inspiration volume and respiratory frequency. In addition, the actual patient flow is calculated by subtracting the leakage flow. If an oxygen sensor is present, the oxygen content of the inspiration air FiO_2 is measured.
The pressure or flow sensor detects the patient's spontaneous respiration and sets off the triggers, which compensate mask leaks. The sensitivity of the trigger is adjustable. The inspiration trigger is a pressure or volume trigger. The expiration trigger is a flow trigger, which is set as a percentage of the maximum inspiration flow.

Alarms

The alarm conditions are continuously checked. In the event of an alarm, an alarm tone sounds and the corresponding message appears on the display. The alarm button also lights up depending on the priority of the alarm. If the alarm conditions are no longer present, the alarm sound is switched off. The message is displayed until the alarm is confirmed by pressing the alarm button on the display. All alarms are saved in the device. For further information about the alarms, refer to “Alarms and error messages”, as of page 75.

NURSE CALL AND REMOTE ALARM

To monitor the device during ventilation, the optionally available remote alarm box or in-hospital nurse call can be connected to the rear of the device (see page 33) in order to forward the alarms.

VENTILATION MODES

Depending on the tube system used, the following ventilation modes can be set in the device.

Valve tube system	
Mode	**Description**
PCV	Pressure Controlled Ventilation
APCV	Assisted Pressure Controlled Ventilation
PSV	Pressure Supported Ventilation
PSV-S	Pressure Supported Ventilation - Spontaneous
CPAP	Continuous Positive Airway Pressure

Table 1: Valve tube system ventilation modes

Leakage tube system	
Mode	**Description**
CPAP	Continuous Positive Airway Pressure
S	Spontaneous Ventilation
T	Timed Ventilation
ST	Spontaneous and Timed Ventilation

Table 2: Leakage tube system ventilation modes

PCV MODE

In the PCV mode, the ventilation is controlled exclusively through the device. The patient is unable to breathe spontaneously. For controlled ventilation, the inspiration trigger must be set to “OFF”. The respiratory cycle is based on the set frequency and a set I:E ratio. The inspiration pressure (IPAP) and end expiration pressure (PEEP) define the pressure range in which the patient is ventilated. The pressure increase can be selected by setting a ramp. The inspiration volume adjusts itself to the condition of the lungs (compliance and resistance). To safeguard a minimum volume (Vt min), a value can be preset, with the option of using additional pressure (IPAP + additional pressure) to reach this minimum volume.

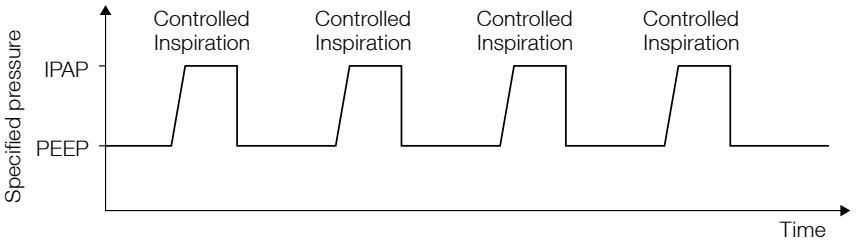


Fig. 3: PCV mode diagram

In the PCV mode, the maximum and minimum volumes, as well as a maximum frequency, can be set as alarm parameters.

APCV MODE

The adjustable ventilation parameters in pressure controlled assisted ventilation, correspond to those in purely controlled ventilation. By setting an inspiration trigger, the patient has the option to interrupt expiration and trigger the next inspiration, by making an effort to breathe and reach the trigger threshold. These additional breaths are, as in purely controlled ventilation, controlled exclusively through the device. The inspiration time is predefined. The patient's own respiratory effort is only able to shorten the expiration time and thereby increase the set frequency.

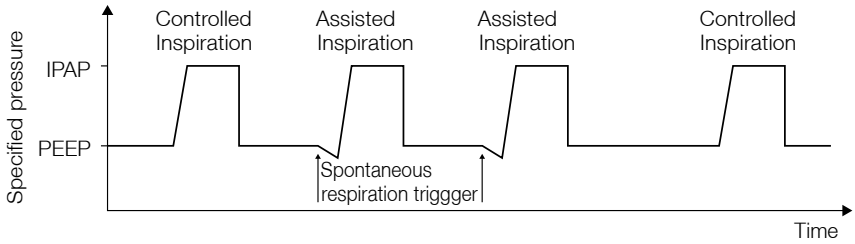


Fig. 4: APCV mode diagram

In the APCV mode, the maximum and minimum volumes, as well as a maximum frequency, can be set as alarm parameters.

PSV MODE

Pressure supported ventilation is intended to support spontaneous breathing and to initiate machine ventilation whenever spontaneous respiration fails. The support pressure (IPAP) and expiration pressure (PEEP) define the pressure range in which the patient is ventilated. The trigger thresholds of the inspiration trigger and the expiration trigger can be adjusted to the patient's requirements. The adjustable frequency is a background frequency. As long as this frequency is reached or exceeded through the patient's spontaneous respiration, the device reacts to every spontaneous inspiration with supportive pressure and follows the patient's breathing. If the background frequency is not reached, the device takes over the mechanical ventilation until spontaneous respiration is registered again. To allow pauses between the spontaneous respiratory efforts of the patient, a delay of the time of the start of mechanical respiration is possible, by setting an apnea limit. The increase in pressure between PEEP and IPAP can be selected by setting a ramp, which prescribes the form of the flow curve. The tidal volume adjusts itself to the condition of the lungs (compliance and resistance). To safeguard a minimum volume, a value can be preset, with the option of using additional pressure (IPAP + additional pressure) to reach this minimum volume.

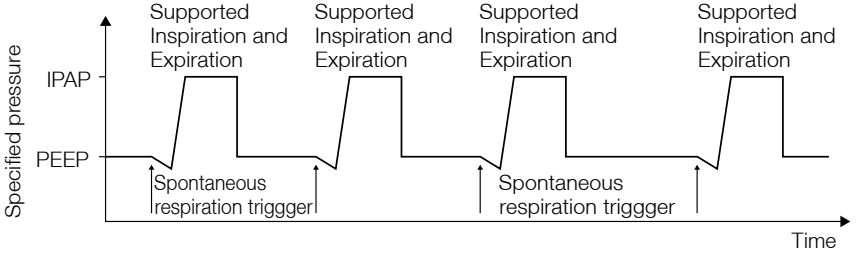


Fig. 5: PSV mode diagram

In the PSV mode, the maximum and minimum volumes, as well as a maximum frequency, can be set as alarm parameters.

PSV-S MODE

The PSV-S mode corresponds to the adjustable ventilation parameters of the PSV mode. As the frequency is set to “OFF”, the trigger is only released when the patient breathes spontaneously. The apnea limit automatically becomes an alarm parameter.

IMPORTANT
In this setting, the device only reacts to the patient’s spontaneous respiration

CPAP MODE

In the CPAP mode, the device provides continuous positive pressure.

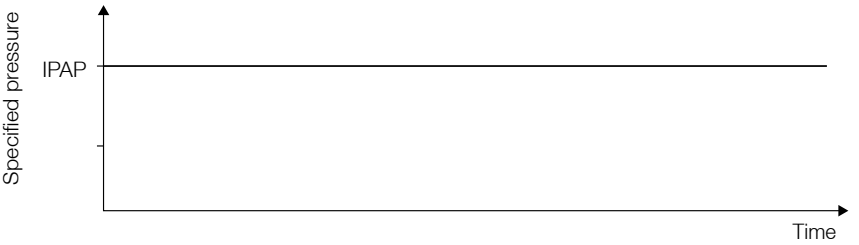


Fig. 6: CPAP mode diagram

S MODE

In its adjustable ventilation parameters, the S mode corresponds to the PSV-S mode.

T MODE

In its adjustable ventilation parameters, the T mode corresponds to the PCV mode and with a set inspiration trigger to the APCV mode.

ST MODE

In its adjustable ventilation parameters, the ST mode corresponds to the PSV mode.

DESCRIPTION OF DEVICE

HOUSING, DISPLAY AND CONTROL ELEMENTS

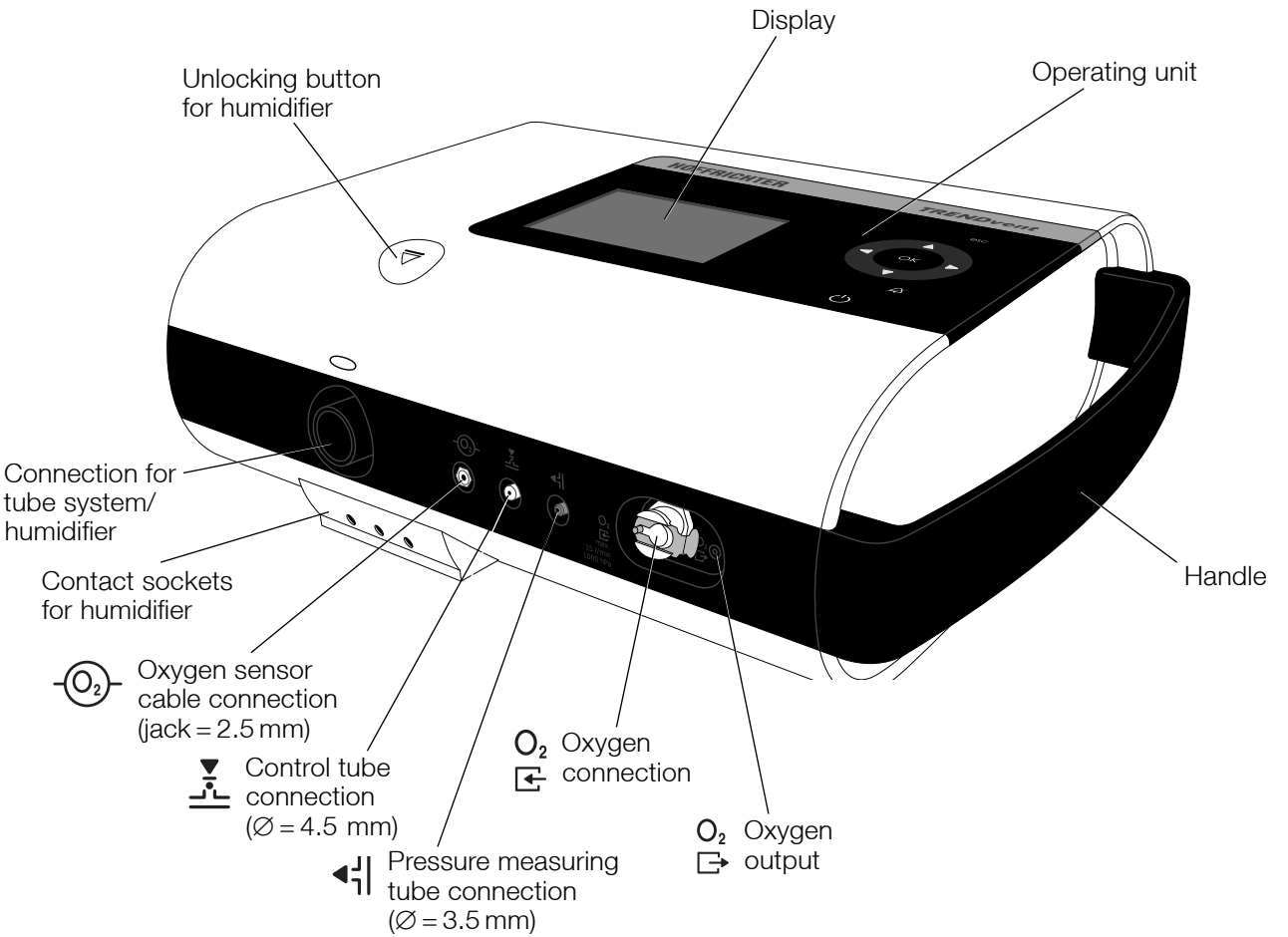

Display
Unlocking button for humidifier
Operating unit
Connection for tube system/ humidifier
Contact sockets for humidifier
Handle
Oxygen sensor cable connection (jack = 2.5 mm)
Control tube connection (∅ = 4.5 mm)
Pressure measuring tube connection (∅ = 3.5 mm)
O2 Oxygen connection
O2 Oxygen output

Fig. 7: Front view of device

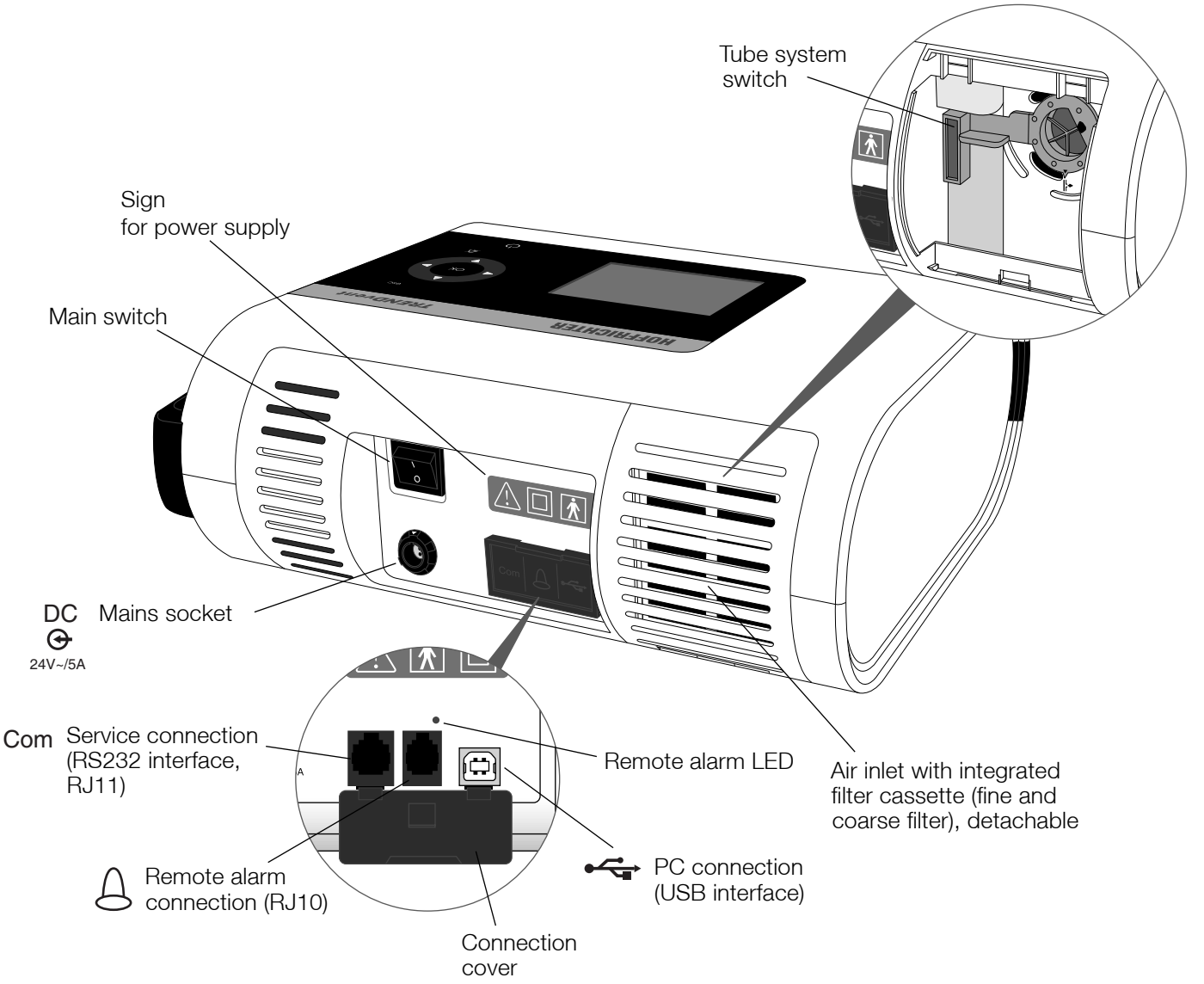


Fig. 8: Rear view of device

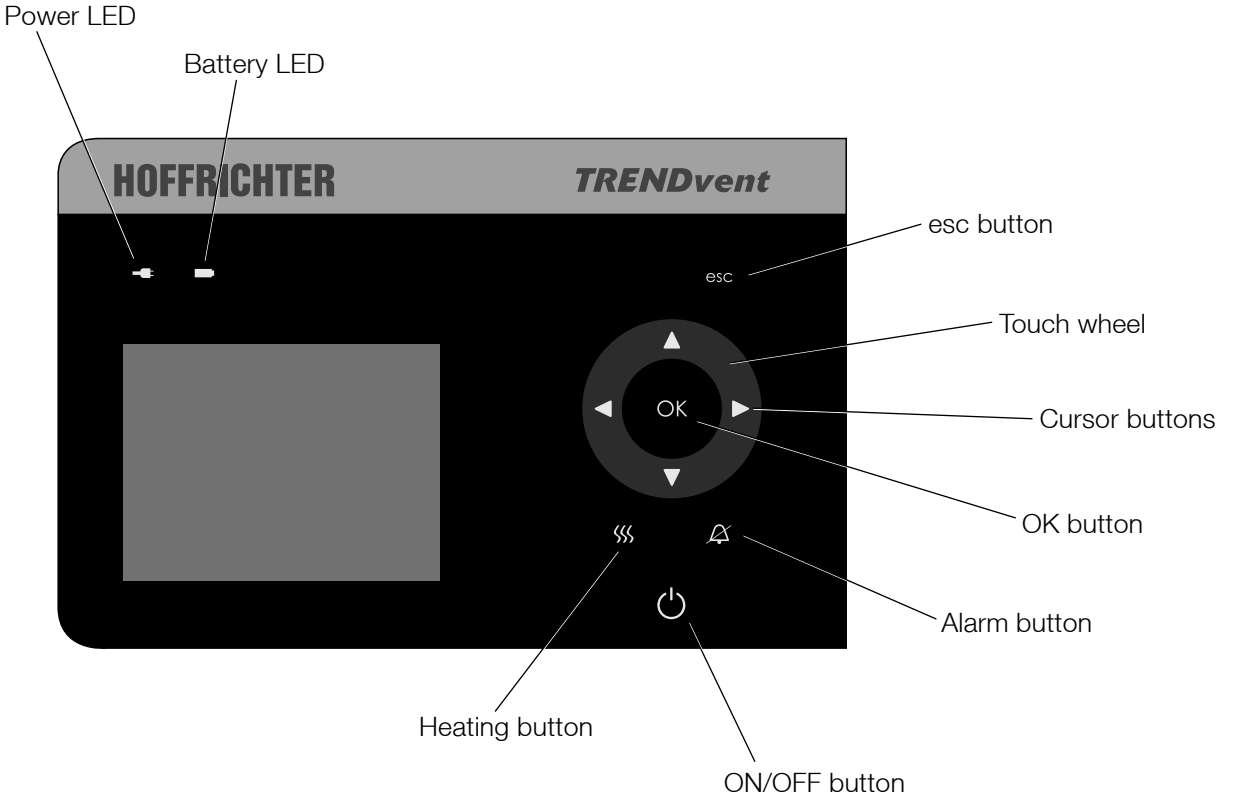


Fig. 9: Operating unit elements

Power LED

The power LED provides information about the power supply.

Color	Condition	Power supply
green	lit	Voltage > 22.0 V
red	flashing	Voltage < 22.0 V
none	off	Voltage > 22.0 V (confirmed)

Table 3: Power LED

Battery LED

The battery LED provides information about the capacity of the internal battery.

Color	Condition	Device	Capacity
green	lit	on	> 80 %
yellow	lit	on	> 30 %
red	lit	on	< 30 %
red	flashing	on	Battery error
green	flashing	off	> 80 % (Battery charging)
yellow	flashing	off	> 30 % (Battery charging)
red	flashing	off	< 30 % (Battery charging)
yellow	lit	off	Battery charging error (capacity < 80 %)
red	lit	off	Battery charging error (capacity < 30 %)

Table 4: Battery LED

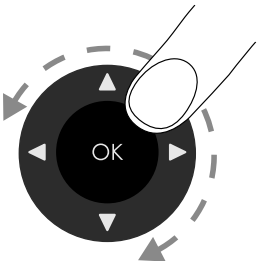
BUTTON FUNCTIONS

esc button

Essentially, the esc button has the following functions:

- Cancel calibrations, parameter changes or similar. The set values are not applied. The old values are retained.
- Cancel marking a parameter.
- Switching the display to the superordinate screen, up to the patient screen.
- In the curve screen, return to the patient screen.

Touch wheel



Use the touch wheel to navigate in a rotary motion through the menus and to the menu items. The touch wheel can also be used to change parameter values.

Cursor buttons

Use the cursor buttons to navigate through the menus and menu items by touch. The cursor buttons can also be used to change parameter values.

OK button

Use the OK button to select menu items and confirm parameter changes. Pressing the OK button in the patient screen, displays the curve screen.

Heating button

The heating button switches the humidifier heating on and off. The heating button also provides information about the status of the heating.

Color	Condition	Status
green	lit	Heating on
green	flashing	Heating in Standby mode
white	lit	Heating off
white	flashing	Heating deactivated by battery operation

Table 5: Heating button

Alarm button

The alarm button has a number of functions:

Event	Condition
Confirmation of a power failure alarm	Power failure
Confirmation of all current alarms and switching alarm sound off	Active alarms
Confirmation of no longer active alarms	Saved alarms
Supressing the alarm sound for 2 min	None
Cancel alarm sound suppression	Paused alarm sound (mute)

Table 6: Alarm button functions

If several of these events occur at the same time, pressing the button confirms only one event, in the order shown above.

The alarm button also signals alarms and their priority.

Color	Condition	Priority
red	flashing	HIGH
yellow	flashing	MEDIUM
yellow	lit	LOW or not yet confirmed alarm

Table 7: Alarm button

ON/OFF button

Start and end ventilation by pressing the ON/OFF key.

COMMISSIONING

- Before commissioning the device, read the safety information as of page 10 onwards.
- A functional test must be carried out before every commissioning (see page 88).
- Before commissioning the ventilation system (ventilator, tube, humidifier, etc.), check all connections for leaks, as well as the stability of the connected accessories.
- Never operate the device without the air filter.
- Only use original HOFFRICHTER filters.

If the device was previously in an environment where the air temperature was very different from the operating location, you should wait approximately 1/2 an hour before commissioning until the temperatures have evened out.

SETTING UP THE DEVICE

Place the device on a flat and stable surface. The device can also be operated in an upright position, whereby care should be taken that the air inlet at the rear of the device and all ventilation slots are not blocked.

USING THE FUNCTIONAL BAG

⚠CAUTION

The device must not be operated in bags other than the HOFFRICHTER functional bag. The functional bag is optionally available from HOFFRICHTER as an accessory. In order to ensure the operating safety, the following instructions must be adhered to.

Set the alarm sound to maximum volume ( ).
Make sure that the alarm button is visible through the viewing window and that the bag's ventilation openings are not blocked. The air supply for the device must be guaranteed at all times. Use the bag in such a way that the device is protected from overheating, dust and water. All accessories connected, such as tube, filter, supply lines, etc, must be arranged such that they cannot lead to any impedance or malfunction of the device.

POWER SUPPLY

The ventilator can be supplied with power from 3 different sources:

- Power supply from power socket
- Internal battery
- External battery pack (optional accessory)

The ventilator automatically detects which power sources are available. If the device is connected to an external voltage source via the power supply unit, this is always used first, and then the internal battery. The current power source is indicated by the corresponding LED.

MAINS OPERATION

NOTICE

Only the power supply cable supplied may be used for operating the device from the mains.

1. Insert the power plug into the mains socket on the rear of the device.
2. Connect the mains cable to the power supply.
3. Plug the mains cable into a power socket.
4. The power LED lights up green and the battery LED shows the current charge status.
5. Switch the ventilator on using the main switch.

As soon as the ventilator is connected to a power supply of 100 - 240 V (-20 %, +10 %), 50/60 Hz, the power LED lights up green.
The power LED is also lit when the main switch is off, as the internal battery is charged. The charging of the battery is additionally indicated by the illuminated battery LED and, if the device is switched on, the battery symbol is shown on the display.

OPERATION WITH INTERNAL BATTERY

IMPORTANT
To prevent the internal battery from discharging, the device should stay connected to the mains power during standby times.

Charging a completely empty battery takes approximately 4 hours.

If the device is switched on without a connection to the mains power, or the device is disconnected from the mains power during operation, an alarm sounds and the message “Battery Operation” appears. To switch off the alarm sound and delete the message, press the alarm button.

With a fully charged battery, the device can be operated for a maximum of 5.5 hours. The battery LED (see page 35) and the battery symbol (see page 58) provide more information about the battery’s capacity.

⚠CAUTION
If the alarm “Internal Battery low” appears, the ventilator must immediately be connected to an alternative power source.

POWER FAILURE

IMPORTANT
During a power failure, the battery capacity display must be monitored and an alternative power source kept ready. For further details on the display of the battery capacity, please refer to page 35.

If the power supply is interrupted by a power failure, the device is supplied with power via the internal battery.

Power failure and thus the switch to the internal battery is indicated by an alarm sound, as well as by the message “Battery Operation” (see Fig. 10). In addition, the power LED will glow red and the alarm button will glow orange.

To switch the alarm off, press the alarm button. The alarm sound is switched off, the message “Battery Operation” is hidden, and the power LED goes out.

When the power supply returns, the device is supplied with power from the mains supply and the internal battery is charged and the power LED is lit green again.

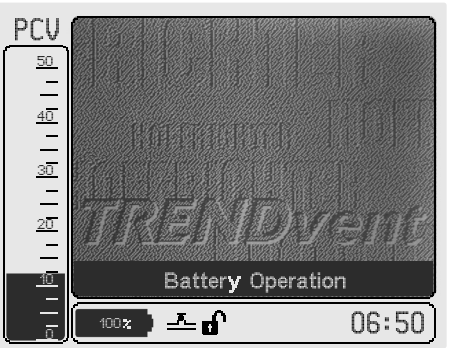


Fig. 10: Message “Battery Operation”

OPERATION WITH EXTERNAL BATTERY

IMPORTANT
Before initial commissioning, you must read the user’s manual for the external battery pack.

The AKKUPACK uni or the AKKUPACK CARAT enable the device to be operated independently of the mains power supply. The battery pack is optionally available as an accessory.

To supply the battery pack with power, use the mains cable and the power supply unit of the ventilator. If the battery pack is connected to the ventilator, the power LED lights green.

At full capacity and factory settings, the battery pack enables operation for a maximum of 12 h.

For further information on connecting and handling the device, please refer to the respective user’s manual.

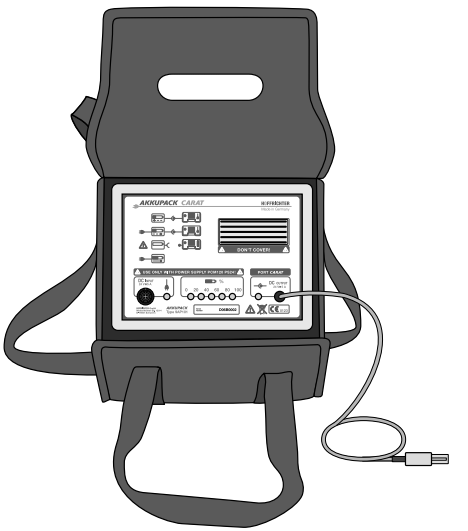


Fig. 11: AKKUPACK CARAT

SETTING THE TUBE SYSTEM

The device is suitable for use with a valve tube system, as well as for use with a leakage tube system. Before using the device for the first time, or if switching to a different tube system, the type of tube system to be used must be set on the device. To do this, proceed as follows:

1. Ensure that the device is switched off.
2. Remove the cover for the air inlet by gripping the cover from below and pulling it from the device (see Fig. 12).
3. Set the switch to the correct position:
   - For the use of a valve tube system, place the switch, by gently lifting and turning, into the lower position (see Fig. 13).
   - For the use of a leakage tube system, place the switch, by gently lifting and turning, into the upper position (see Fig. 14).
4. Replace the cover for the air inlet.

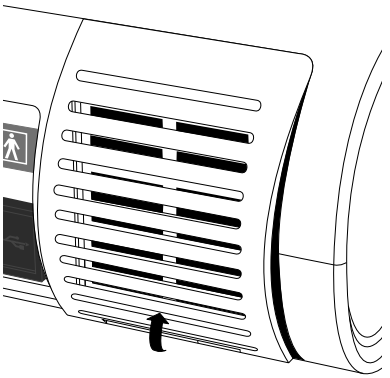


Fig. 12: Removing the air inlet cover

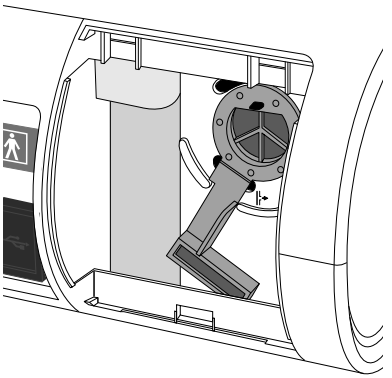


Fig. 13: Switching to valve tube system

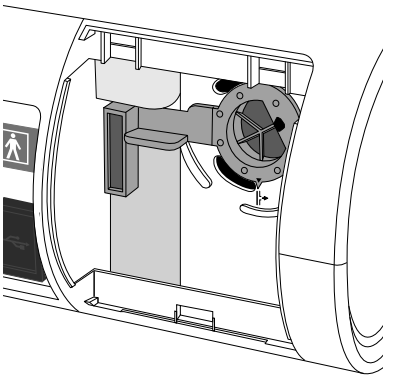


Fig. 14: Switching to leakage tube system

When you switch the device on after switching to a different tube system, the display indicates which tube system is active. Press the OK button to reach the patient screen.

CONNECTING THE VALVE TUBE SYSTEM

The valve tube system consists of:

a Ventilation tube
b Expiration valve
c Patient connection
d Air outlet
e Device connection
f Valve control tube for the expiration valve
g Pressure measuring tube

Connect the valve tube system as follows:

1. Ensure that the device has been set up for the use of a valve tube system (see page 43).
2. Attach the ventilation tube with the device-connection side to the device's tube connection.
3. Attach the valve control tube for the expiration valve to the control tube connection.
4. Attach the pressure measuring tube to the pressure measuring tube connection.

IMPORTANT

When a nasal or full-face mask is used for non-invasive ventilation, this mask must not contain an expiration opening.

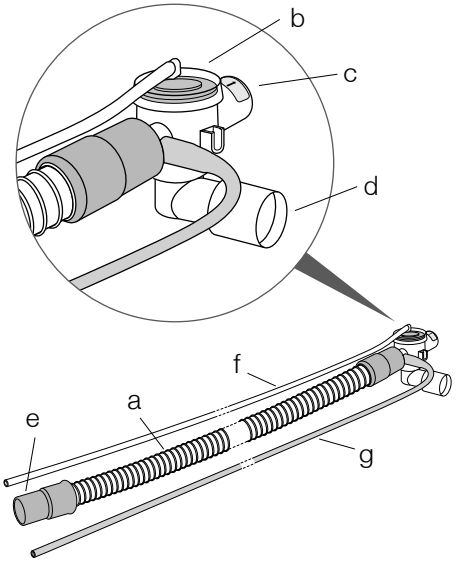


Fig. 15: Valve tube system

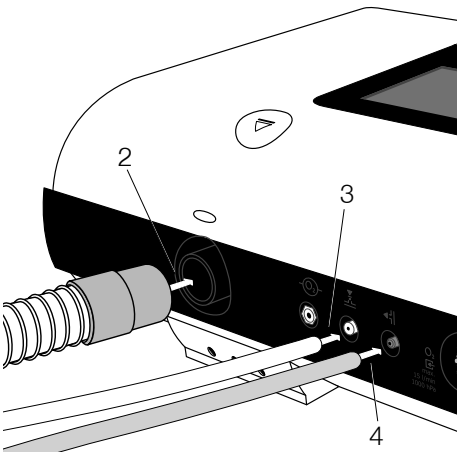


Fig. 16: Valve tube system connection

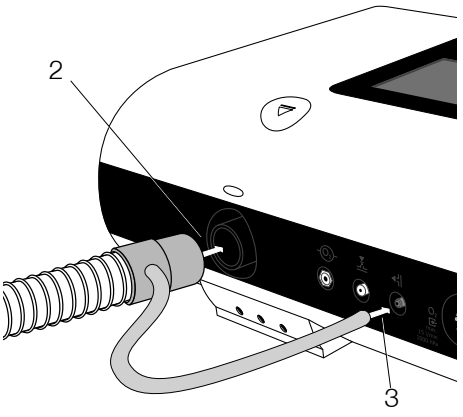


Fig. 17: Leakage tube system connection

CONNECTING THE LECKAGE TUBE SYSTEM

Connect the leakage system as follows:

1. Ensure that the device has been set up for the use of a leakage tube system (see page 43).
2. Attach the leakage tube system with the device-connection side to the device's tube connection.
3. Attach the pressure measuring tube to the pressure measuring tube connection ◂┤.

The leakage system must always provide the possibility for exhalation. Exhalation may either be possible via a respiratory mask with an integrated exhalation valve, or a separate exhalation system.

⚠WARNING

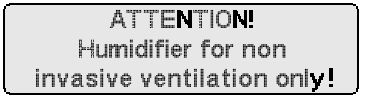
The expiration valve must be open during ventilation. Ensure that the opening is not covered, as the expiration air can otherwise not escape and thereby hinder ventilation.

CONNECTING THE HUMIDIFIER

⚠WARNING
The AquaTREND uni humidifier must not be used for invasive ventilation.

The AquaTREND uni humidifier can be used to humidify the respiratory air.

1. Connect the humidifier to the device as in Fig. 18 until it locks into place. Ensure that the contact pins and the air outlet of the humidifier are fitted to the device without being skewed and distorted. If the device is set for operation with a valve tube system, the following message appears:



2. Confirm the message by pressing the OK button.
3. Attach the ventilation tube to the humidifier's tube connection.

IMPORTANT
It is imperative that, before using the AquaTREND uni humidifier, you read the safety and cleaning instructions in the user's manual.

The humidifier can only be used up to a pressure of max. 20 hPa.

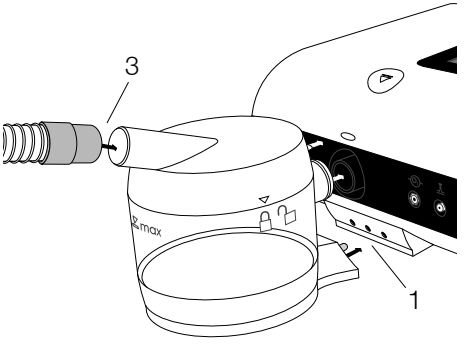


Fig. 18: Humidifier connection

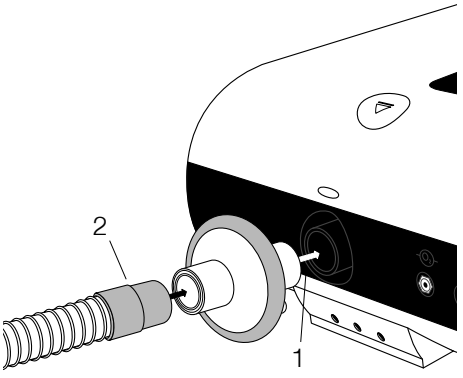


Fig. 19: Bacterial filter connection

CONNECTING THE BACTERIAL FILTER

To protect the patient from infection during patient changes, we recommend the use of bacterial filters. Connect the bacterial filter as follows:

1. Attach the bacterial filter to the device's tube connection.
2. Connect the device-connection side of the tube system with the bacterial filter.

IMPORTANT

Change the bacterial filter daily and follow the manufacturer's user's manual.

If the optionally available AquaTREND uni humidifier is used during ventilation, a bacterial filter may not be used.

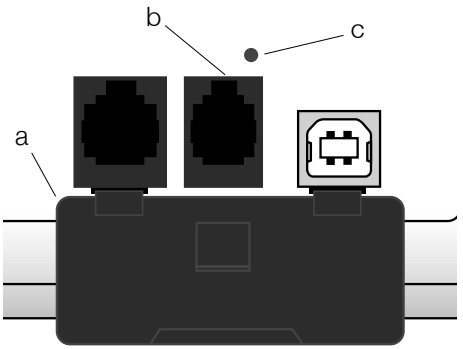


Fig. 20: Remote alarm/ nurse call connection

CONNECTING THE REMOTE ALARM BOX/NURSE CALL

1. Pull off the rubber cover (a) on the rear of the device.
2. Attach the remote alarm box/nurse call to the middle socket (b).

If a remote alarm box is connected, the remote alarm LED (c) lights up red when an alarm occurs. The light indicates that the alarm has been forwarded to the remote alarm box.

SWITCHING THE DEVICE ON

IMPORTANT

An sound must be emitted when the device is switched on. If this is not the case, the device must not be used and should be checked by an authorized service technician.

The tube system may already be connected when the device is started, but not yet connected to the patient.

Switch the ventilator on using the main switch at the rear of the device (position “I”).

- A signal sounds.
- A hardware test is carried out internally and the parameters are tested for plausibility. If the hardware test is successful, the device switches to the patient screen.
- In case of an error, the status screen is displayed and the error is indicated by the display “Error”.
- The device carries out a self-test of the alarm button. The button lights up in the following order: white > red > yellow > white. The light subsequently goes out.

After switching on, the device is in standby mode.

If using oxygen during ventilation, observe the chapter “Using oxygen” on page 52.

SWITCHING THE DEVICE OFF

1. Stop ventilation by pressing the ON/OFF button. A signal sounds and the display shows the query:

2. Press the cursor ◀ to select “Yes”, followed by the OK button. Subsequently, a signal sounds 3 times and the ventilation stops.
3. Switch the ventilator off using the main switch on the rear of the device (setting “0”).

IMPORTANT
After switching off, all parameters set are retained.

If you switch off the device during running ventilation, a signal sounds and the display shows the query:

Continue ventilation:

1. Press the OK button. The message “ATTENTION! Main Switch OFF” appears .
2. Switch the ventilator on again using the main switch.

Stop ventilation:

1. Press the cursor ◀ to select “Yes”.
2. Press the OK button. Subsequently, a signal sounds 3 times and the ventilation stops.

STARTING VENTILATION

⚠WARNING
The expiration valve must be open during ventilation. Ensure that the opening is not covered, as the expiration air can otherwise not escape and thereby hinder ventilation.

1. Switch the ventilator on.
2. Press the ON/OFF button. Ventilation starts.
   The ON/OFF button lights up green and the pressure bar can be seen in the patient screen. If the patient screen is not active, the current ventilation parameters are shown at the bottom of the display.

STOPPING VENTILATION

1. Press the ON/OFF button during running ventilation. A signal sounds and the display shows the query:

2. Press the cursor ◀ to select “Yes”, followed by the OK button. Subsequently, a signal sounds 3 times and the ventilation stops.

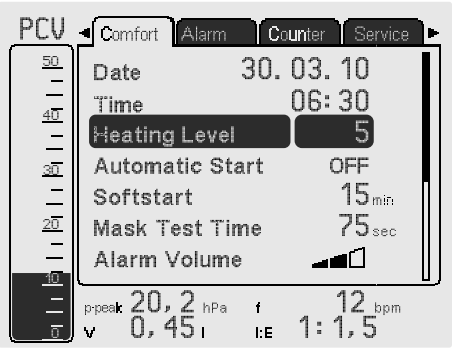


Fig. 21: Setting Heating Level

OPERATION WITH HUMIDIFIER

Connect the AquaTREND uni humidifier as described on page 46. The humidifier features an integrated heating system for heating the humidifier water. This enables the respiratory air to be preheated.

SETTING THE HUMIDIFIER HEATING LEVEL

1. Activate the comfort screen using the cursors ◀ or ▶.
2. Select “Heating Level” using the cursor ▼ or touch wheel.
3. Press the OK button.
4. Set the desired heating level using the cursors ▲ or ▼ or the touch wheel. You can select a value between 1 to 5. Level 1 represents the lowest heat output and level 5 represents the maximum heat output.
5. Confirm the settings using the OK button.

SWITCHING ON THE HEATING

To switch on the humidifier’s heating, press the heating button (function description see page 36). The color of the heating button changes from white to green. If the heating is in standby mode (heating button flashing green) and you start ventilation, the heating is automatically started.

IMPORTANT

You can switch on the heating before starting ventilation in order to preheat the water.

SWITCHING ON THE HEATING

To switch the heating off, press the heating button. The color of the heating button changes from green to white.
If the humidifier is in heating mode during ventilation and you stop ventilation, the humidifer’s heating automatically switches to standby mode (heating button flashes green). As soon as you start the ventilation, the heating is also re-activated.

USING OXYGEN

⚠WARNING
Before using oxygen, the safety instructions as of page 16 must be read.

The supply of oxygen is possible in all ventilation modes. Please note that changes to the ventilation parameters, such as e.g. respiratory pressure, I:E, respiratory frequency, will lead to a change in FiO_2 content.

NOTICE
Oxygen may only be supplied during active ventilation.

SUPPLYING OXYGEN

1. Connect the tube from the oxygen source to the oxygen connection adapter.
2. Insert the oxygen connection adapter into the oxygen connection (O_2).

   NOTICE
   Only the oxygen connection adapter supplied may be used to connect oxygen. Otherwise, there is a risk that the back-stop in the connection is damaged.

3. Switch the device on.
4. Start ventilation and wait for several respiratory cycles.
5. Start supplying the oxygen.

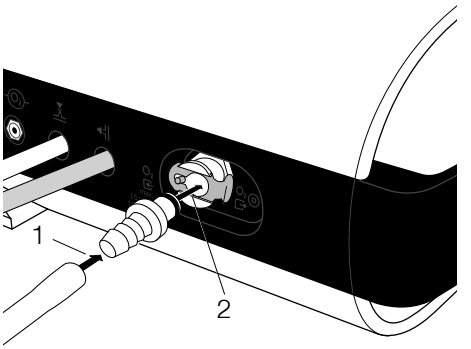


Fig. 22: Oxygen connection

STOPPING THE SUPPLY OF OXYGEN

1. Stop the supply of oxygen at the oxygen source.
2. Allow ventilation to continue for a number of respiratory cycles.
3. Stop ventilation.

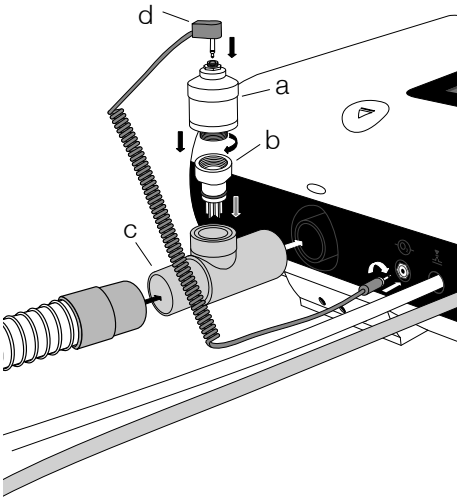


Fig. 23: Oxygen sensor connection

MEASURING OXYGEN CONCENTRATION

Oxygen can only be measured in combination with a valve tube system with an expiration valve. Use the optionally available oxygen sensor for this. Depending on the ambient conditions, the sensor can require up to 30 minutes after installation to reach signal stability.

1. Ensure that the ventilator is switched off.
2. Screw the oxygen sensor (a) into the housing gas duct (b).
3. Insert the gas duct with the oxygen sensor into the T-adapter (c).
4. Insert the T-adapter into the device's tube connection.
5. Connect the device-connection side of the ventilation tube with the T-adapter.
6. Insert the angled plug of the connection lead (d) into the oxygen sensor at the top and the straight plug into the oxygen measuring tube connection -(O_2)-. The alarm button lights up yellow.
7. Switch the ventilator on. When the device is started, the oxygen sensor is automatically calibrated and the alarm button is no longer lit. It is calibrated against the ambient air. This presumes an oxygen content of 21 %. If the sensor is connected after the device is started, the message "Calibrate O2 Sensor" appears on the display. The calibration of the oxygen sensor must now be started manually.
   1. Ensure that the device is in standby mode.
   2. Press the OK button. "Start O2 Sensor Calibration" appears on the display.
   3. Press the OK button. After successful calibration, "OK" appears after several seconds. If calibration was not successful, "Error" appears. In the event of error, repeat the calibration. Should this not be successful, exchange the oxygen sensor.

IMPORTANT

If the contact between the oxygen sensor and the device is interrupted for more than 10 seconds, the O_2 sensor calibration must be carried out again.

NOTICE

Oxygen sensors have a limited durability. A durability of 15 months after the date of manufacture applies for oxygen sensors supplied by HOFFRICHTER. The service life of the sensors is 6 months. After that, the oxygen sensor must be replaced by a new one. The date of manufacture can be found on the oxygen sensor.
For the longest possible sensor service life, we recommend storage at - 15 °C to + 5 °C.

OPERATING THE DEVICE

OPERATING CONCEPT

The device is operated via the controls on the operating unit. The principal operating structure is represented in the following figure. As soon as your hand comes near to the operating unit, the control elements and the display light up.

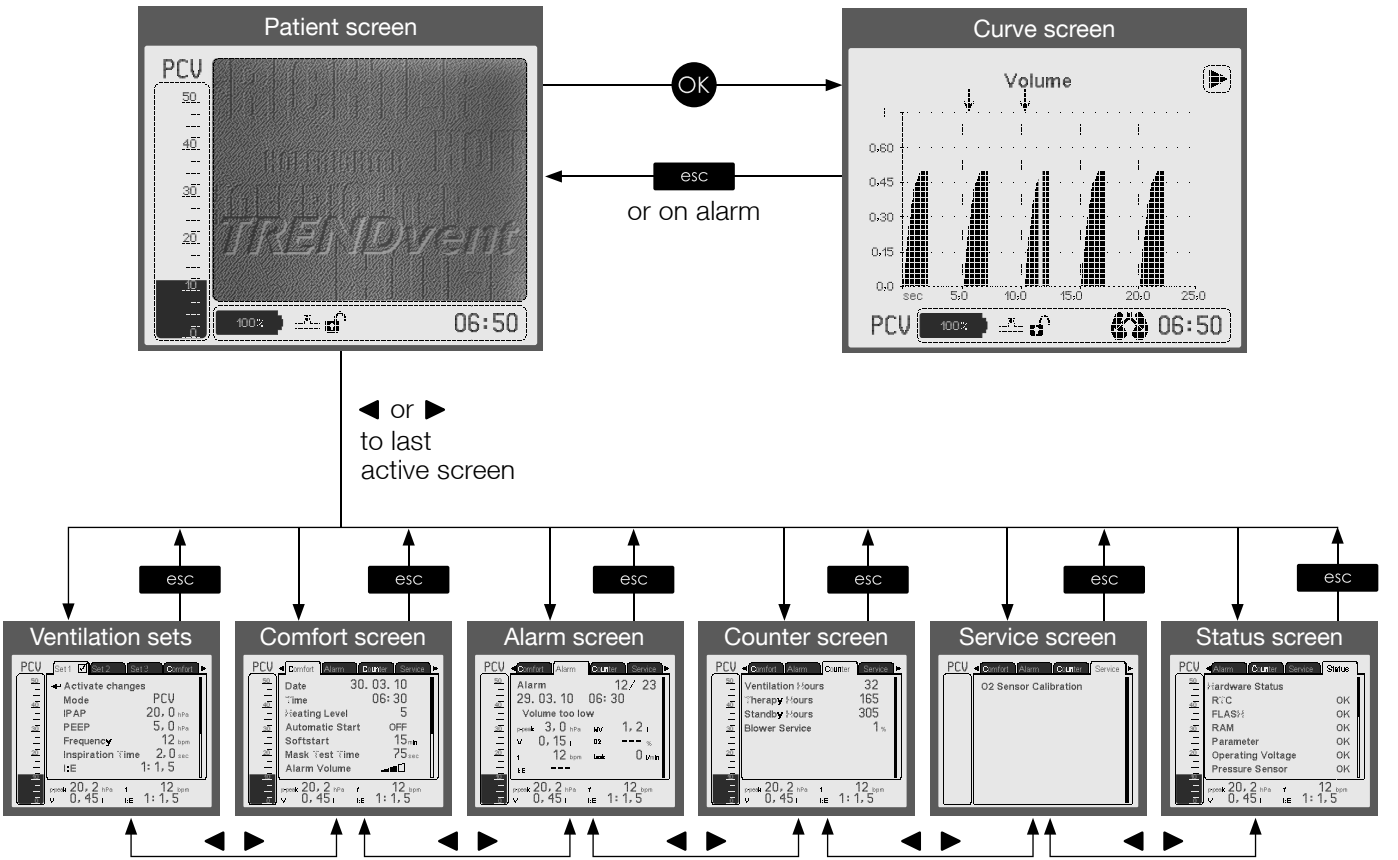


Fig. 24: Operating concept

CHANGING SCREENS

Press the cursors ◀ or ▶ to switch to the previous or next screen. If the patient screen is active, pressing the cursors ◀ or ▶ displays the last screen selected.

SAFETY LOCK

To protect against accidental or unauthorized alteration of the ventilation and alarm parameters, the device features a safety lock. Apart from switching to the curve and patient screens, no actions can be carried out if the safety lock is activated. Changing the ventilation parameters in the curve screen is also not possible.

IMPORTANT

The safety lock can only be activated and deactivated in the patient screen.

ACTIVATING THE SAFETY LOCK

The safety lock can be activated manually or automatically after a defined period of time.

Manual activation of the safety lock:

1. Press the esc button. appears alternating in the symbol area.
2. As long as the symbol is visible, press the OK button. Thereupon remains visible and the safety lock is active. If you do not press the OK button, the symbol disappears after several seconds without the safety lock being activated and is then active again.

DEACTIVATING THE SAFETY LOCK

1. Press the esc button. appears alternating in the symbol area.
2. While the symbol is flashing, press the OK button. The symbol subsequently disappears and the safety lock is deactivated and is then active again.

THE PATIENT SCREEN

During normal operation the patient screen is shown on the display. During ventilation the pressure bar provides constant information about the pressure profile. Additionally, all relevant information, such as alarms, battery capacity, status information, etc. is displayed.

IMPORTANT

If no controls are actuated for 30 seconds, the device automatically switches back to the patient screen. In the curve screen, the switch only occurs in case of an alarm.

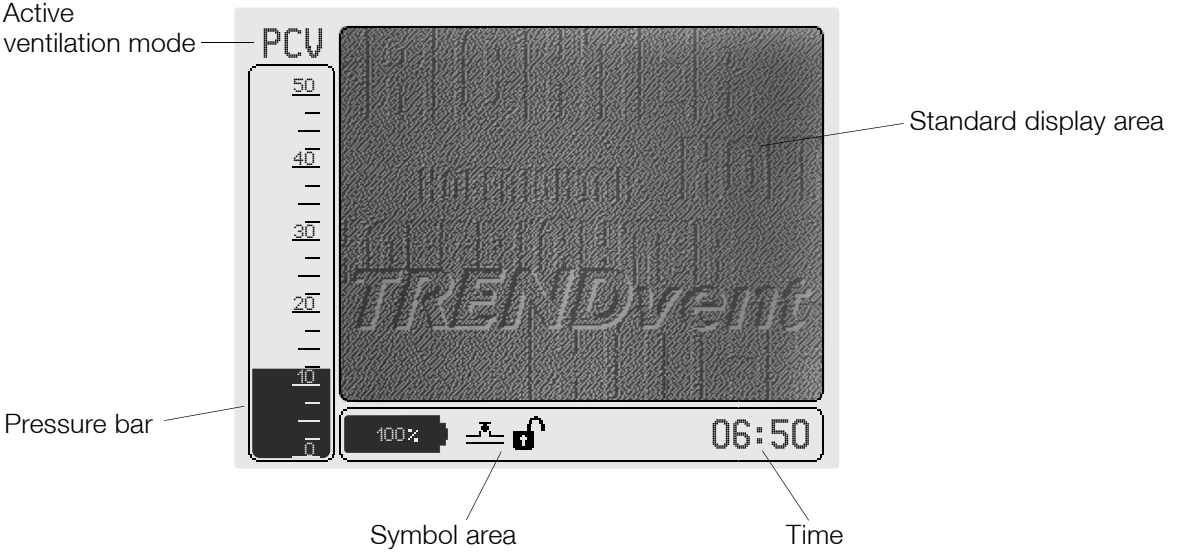
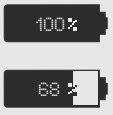
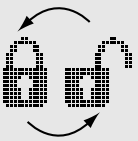


Fig. 25: Patient screen

SYMBOL AREA

Symbol	Meaning
	The symbol indicates the remaining capacity of the internal battery. The battery is charged during mains operation. The constantly filling battery display indicates that the battery is charging.
	The device is set for operation with a valve tube system (see page 43).
	The device is set for operation with a leakage tube system (see page 43).
	The alarm sound has been muted for 2 min. The alarm sound of any new alarm is also muted until the 2 min. have expired. Pressing the alarm button can deactivate the alarm sound before an alarm is triggered. Pressing the button once more activates the alarm sound again when an alarm occurs.
	The safety lock is active.
	The safety lock is inactive.
	A continuous change from a closed to an open lock means that the safety lock can be either activated or deactivated. For further information, refer to page 56 onwards.

Symbol	Meaning
	Once this symbol appears, the device may only continue to be operated for a maximum of 450 hours. Then the blower must be exchanged by Service, at the latest after a running time of 15000 hours (see counter screen > Blower Service: 15000 h ≤ 100 %). The symbol is only displayed if the mask test time or the softstart ramp is not active.
	The symbol indicates that the mask test is active. Once the set mask test time has expired, the symbol vanishes.
	The symbol indicates that the softstart ramp is active. Once the set softstart time has expired, the symbol vanishes. The symbol is only displayed if the mask test time is not active.
	The device has detected spontaneous patient respiration and the trigger has been initiated. The symbol remains visible during the entire inspiration time and vanishes with the start of expiration.

Table 8: Symbol area

THE CURVE SCREEN

The curve screen provides a graphical display of the pressure, volume and flow in the form of a curve chart.
To activate the curve screen from the patient screen, press the OK button. To leave the curve screen and return to the patient screen, press the esc button. In the case of an alarm, the display automatically returns to the patient screen, in order to show the alarm message.

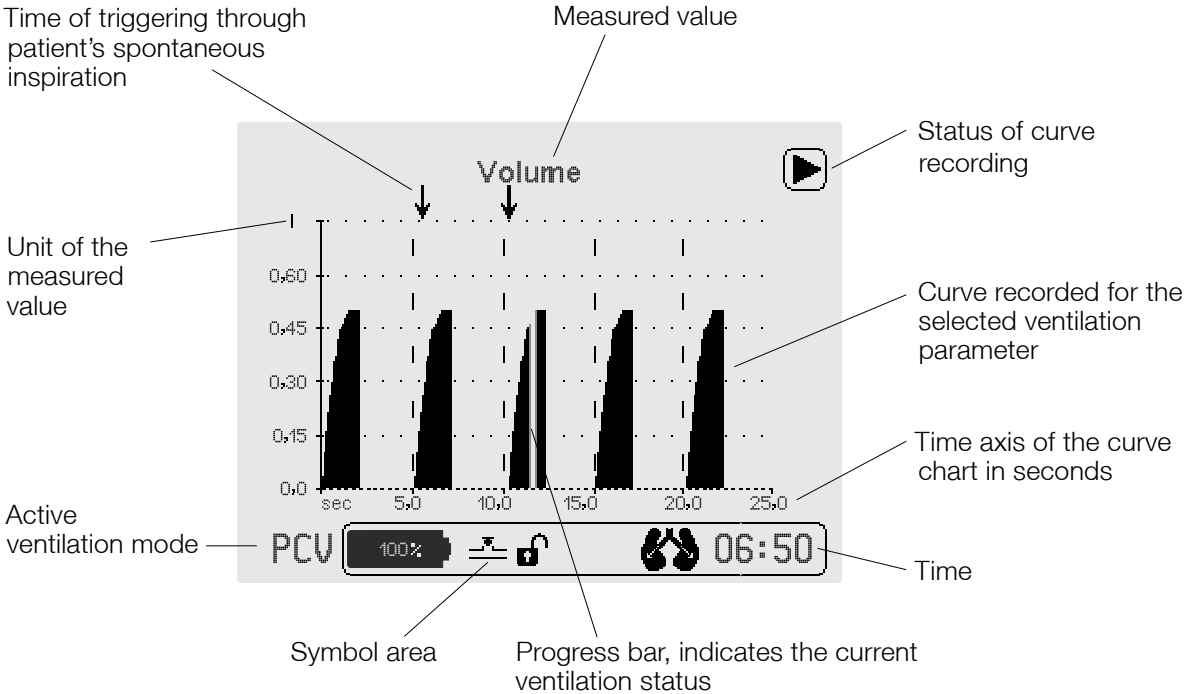


Fig. 26: Layout of the curve screen

Immediately after the activation of the curve screen during ventilation, the curves are set up over the set period of time. The curves are then replaced with the new values. The current ventilation status is shown via a white progress bar.
If a new calculation of the curve starts at the beginning of the time axis, this symbol is briefly shown in the upper right of the screen:

The recording of the curves within the time axis is indicated by the following symbol:

“FREEZING” THE CURVE SCREEN

To analyze and evaluate the curves, it is possible to “freeze” the current curve recording. To do this, press the OK button. This symbol indicates that the curve is “frozen”:

To start recording the curves again, press the OK button. The curve recording subsequently starts again at zero.

SCALING THE TIME AXIS

The scaling of the time axis can be adjusted as follows:

- 0 to 12.5 s,
- 0 to 25 s or
- 50 s.

Press the cursor ◀, to decrease the time span and ▶ to increase the time span.

CHANGING THE MEASURED VALUE

To display the curve chart for a different value, press the cursors ▲ or ▼.

THE VENTILATION SETS

A ventilation set contains all ventilation parameters relevant to ventilation.
A maximum of 3 ventilation sets can be preconfigured by the physician.
Depending on this you have 1 to 3 ventilation sets.

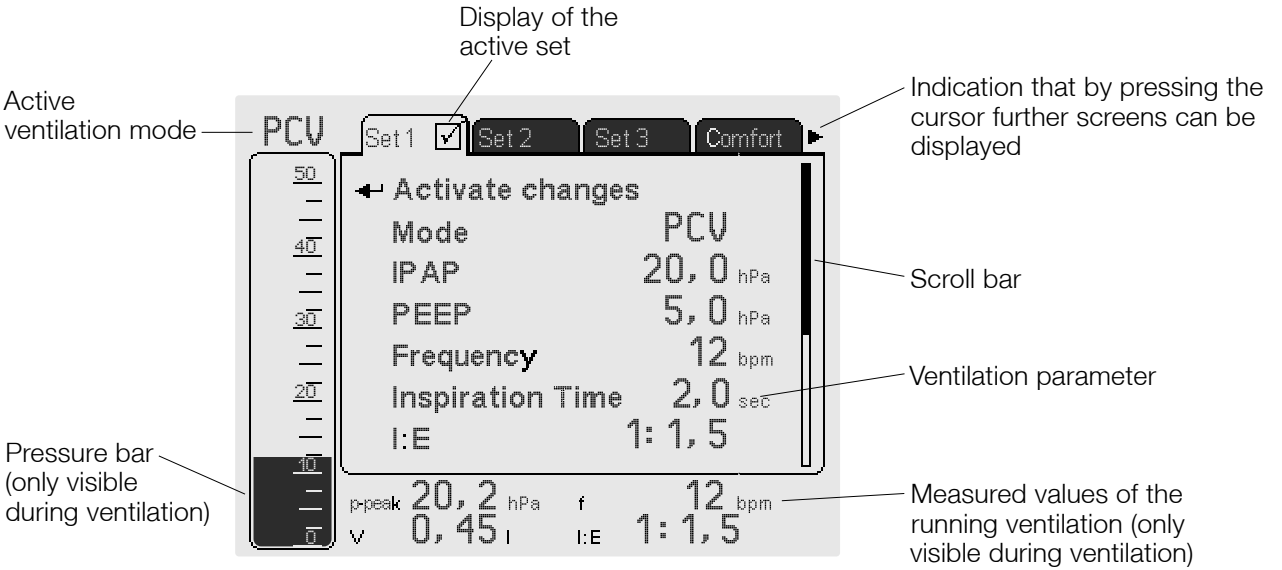


Fig. 27: Ventilation set 1

ACTIVATING THE VENTILATION SET

To ventilate the patient with a ventilation set's settings, the respective ventilation set must be activated. To do this, proceed as follows:

1. Activate the desired ventilation set using the cursors ◀ or ▶.
2. Select "↵ Activate changes" using the cursor ▼ or touch wheel.
3. Press the OK button. This query appears:

4. Press the cursor ◀ to select "Yes", followed by the OK button.

THE COMFORT SCREEN

The comfort screen contains the following basic device settings:

- Date and time
- Volume of alarms
- Brightness and contrast of the display

In addition, the following comfort functions can be set:

- Heating Level
- Automatic Start
- Duration of the softstart ramp (Softstart)
- Duration of the mask test (Mask Test Time)

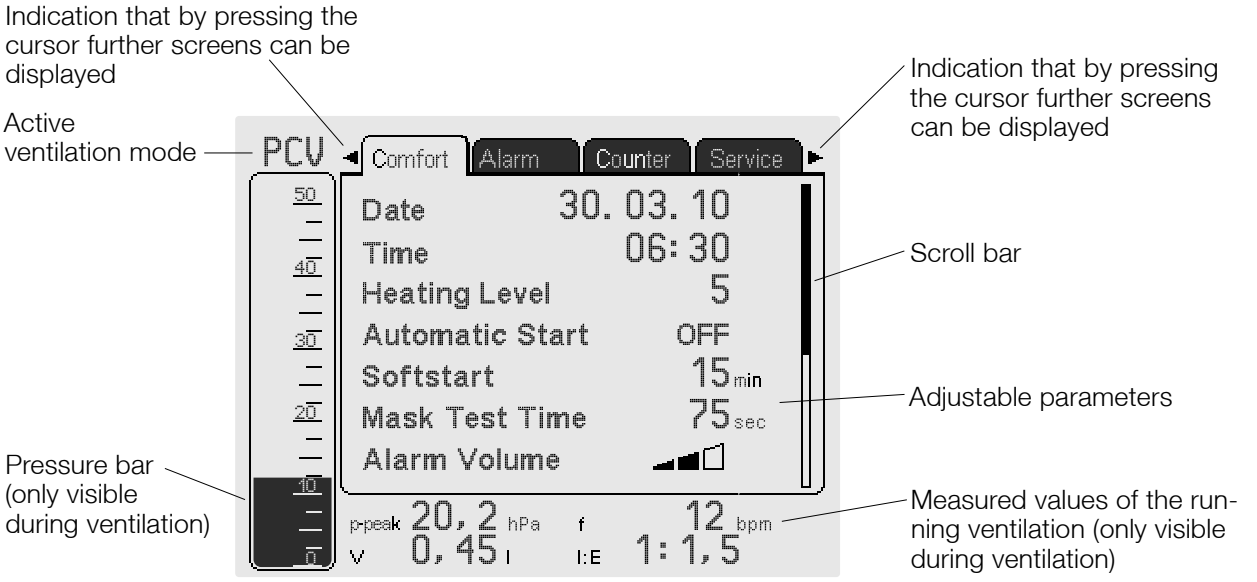


Fig. 28: Comfort screen

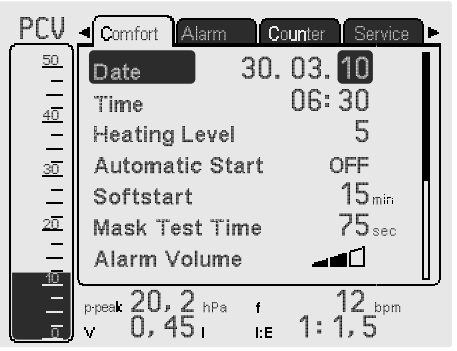


Fig. 29: Changing the date

CHANGING THE DATE

1. Activate the comfort screen using the cursors ◀ or ▶.
2. Select “Date” using the cursor ▼ or the touch wheel.
3. Press the OK button.
4. Set the year using the cursors ▲ or ▼ or the touch wheel.
5. Press the OK button.
6. Set the month using the cursors ▲ or ▼ or the touch wheel.
7. Press the OK button.
8. Set the day using the cursors ▲ or ▼ or the touch wheel.
9. Confirm the settings using the OK button.

IMPORTANT

If, before reaching point 9, you leave the menu item “Date” by pressing the esc button, all changes are lost and the existing date is retained.

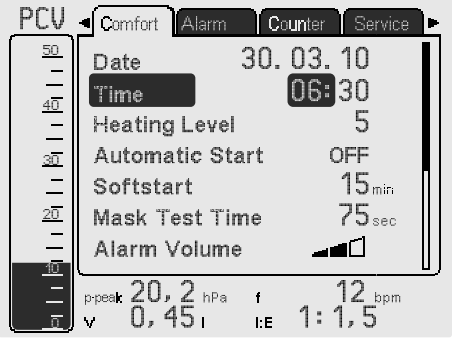


Fig. 30: Changing the time

CHANGING THE TIME

1. Activate the comfort screen using the cursors ◀ or ▶.
2. Select “Time” using the cursor ▼ or touch wheel.
3. Press the OK button.
4. Set the hour using the cursors ▲ or ▼ or the touch wheel.
5. Press the OK button.
6. Set the minutes using the cursors ▲ or ▼ or the touch wheel.
7. Confirm the settings using the OK button.

IMPORTANT

If, before reaching point 7, you leave the menu item “Time” by pressing the esc button, all changes are lost and the existing time is retained.

SETTING THE AUTOMATIC START

The automatic start enables ventilation to be started through the patient's own efforts to breathe. If the mask slips, falls off or uncompensatable leaks occur, ventilation continues and a signal sounds.

1. Activate the comfort screen using the cursors ◀ or ▶.
2. Select "Automatic start" using the cursor ▼ or the touch wheel.
3. Press the OK button.
4. Set the start automatic to "ON" or "OFF" using the cursors ▲ or ▼ or the touch wheel.
5. Confirm the settings using the OK button.

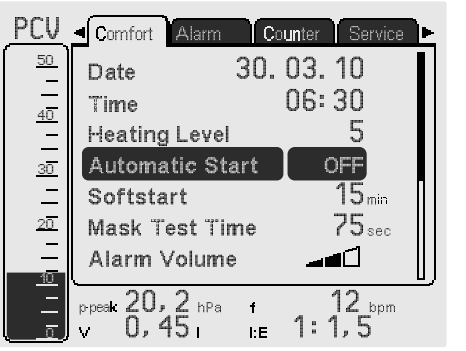


Fig. 31: Setting the automatic start

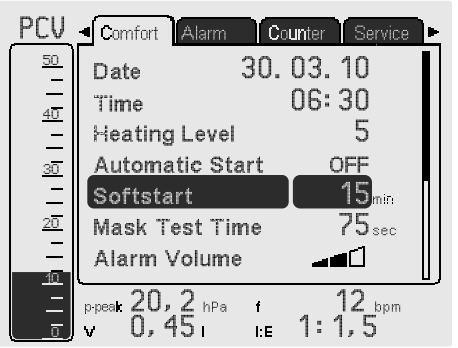


Fig. 32: Setting the softstart time

SETTING THE SOFTSTART TIME

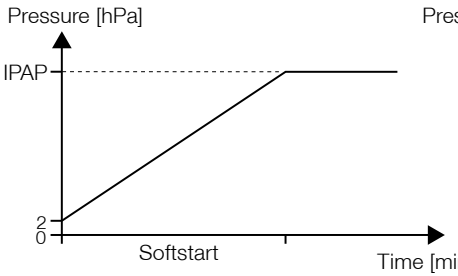
The use of the “Softstart” function can bring some relief if the patient has not really become accustomed to ventilation.
The softstart function slowly increases the pressure in the time programmed by you starting with a defined initial ramp pressure, up to the prescribed pressure.

Ventilation mode	Starting ramp pressure	
	IPAP	EPAP
CPAP	0 hPa	---
(A)PCV, PSV(-S)	4 hPa	0 hPa
S, T, ST	4 hPa	2 hPa

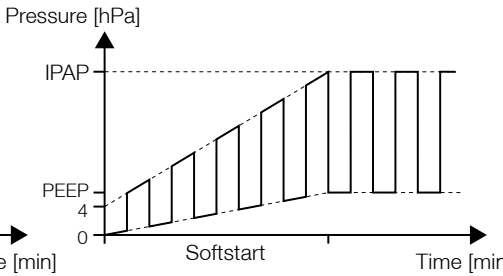
Table 9: Starting ramp pressures

1. Activate the comfort screen using the cursors ◀ or ▶.
2. Select “Softstart” using the cursor ▼ or the touch wheel.
3. Press the OK button.
4. Set the desired time using the cursors ▲ or ▼ or the touch wheel. You can set the time that is set under “Max. Softstart” as a maximum.
5. Confirm the settings using the OK button.

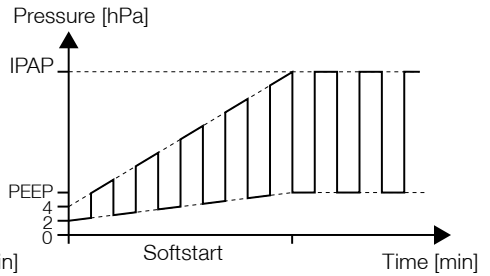
CPAP mode



(A)PCV/PSV(S) - mode



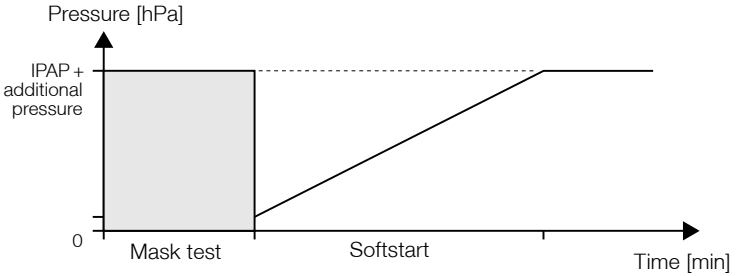
S-/T-/ST - mode



SETTING THE MASK TEST TIME

The mask test time is the period in which the device carries out a mask test. Here, the worn mask is tested for any leakage, at max. pressure (IPAP + Additional Pressure). If the “Softstart” function is active, the mask test is carried out before the softstart ramp begins.

1. Activate the comfort screen using the cursors ◀ or ▶.
2. Select “Mask Test Time” using the cursor ▼ or touch wheel.
3. Press the OK button.
4. Set the desired time using the cursors ▲ or ▼ or the touch wheel. You can select a value between 5 to 90 s. In the “OFF” setting, no mask test is carried out.
5. Confirm the settings using the OK button.



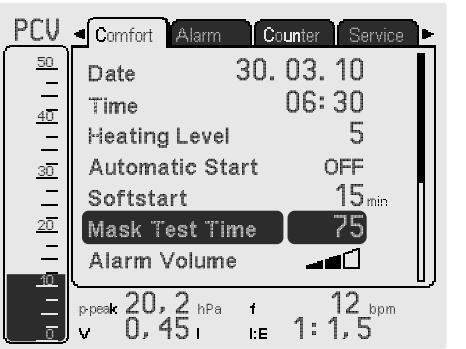


Fig. 33: Setting the mask test time

Fig. 34: Mask test time in the CPAP mode in combination with the “Softstart” function

STARTING THE MASK TEST

To start the mask test, put the mask on and start the ventilation.

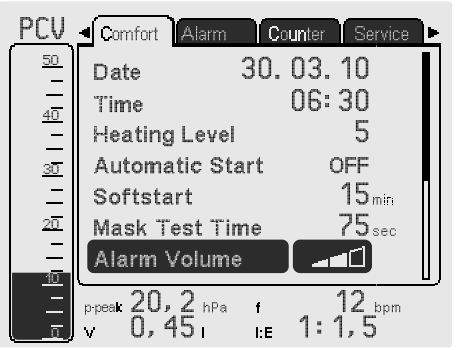


Fig. 35: Setting the volume of the alarms

SETTING THE VOLUME OF THE ALARMS

1. Activate the comfort screen using the cursors ◀ or ▶.
2. Select “Alarm Volume” using the cursor ▼ or the touch wheel.
3. Press the OK button.
4. Set the desired volume using the cursors ▲ or ▼ or the touch wheel. 3 settings are possible:
   = quiet
   = medium
   = loud
5. Confirm the settings using the OK button. An alarm sounds at the set volume.

IMPORTANT

If you do not hear an alarm sound, the device must not be used, as the acoustic alarms may be faulty. Have the device checked by an authorized service technician.

SETTING THE BRIGHTNESS OF THE DISPLAY

During ventilation, the background light of the display is dimmed 30 seconds after touching a button or the occurence of an alarm. You can set this value as follows:

1. Activate the comfort screen using the cursors ◀ or ▶.
2. Select “Brightness” using the cursor ▼ or touch wheel.
3. Press the OK button.
4. Set the desired value using the cursors ▲ or ▼, or the touch wheel. You can set the brightness to “OFF” or select a value between 10 and 100 %.
5. Confirm the settings using the OK button.

When an alarm occurs or a button is pressed, the background brightness is automatically increased to 100 %.

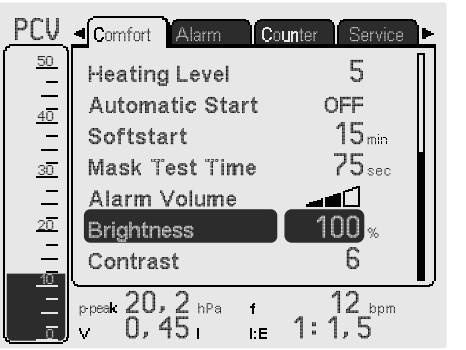


Fig. 36: Setting the brightness of the display

SETTING THE CONTRAST OF THE DISPLAY

The contrast is the brightness ratio between the display background and elements such as text, symbols, diagrams etc.

1. Activate the comfort screen using the cursors ◀ or ▶.
2. Select “Contrast” using the cursor ▼ or touch wheel.
3. Press the OK button.
4. Set the desired value using the cursors ▲ or ▼, or the touch wheel. Values between 1 to 10 are possible. The best contrast is achieved in the middle settings range.
5. Confirm the settings using the OK button.

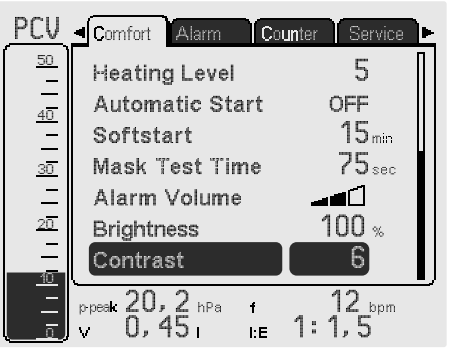


Fig. 37: Setting the contrast of the display

THE ALARM SCREEN

You can view the alarm memory in the alarm screen. For more information about the alarm memory, please refer to “Saving alarms” on page 82.

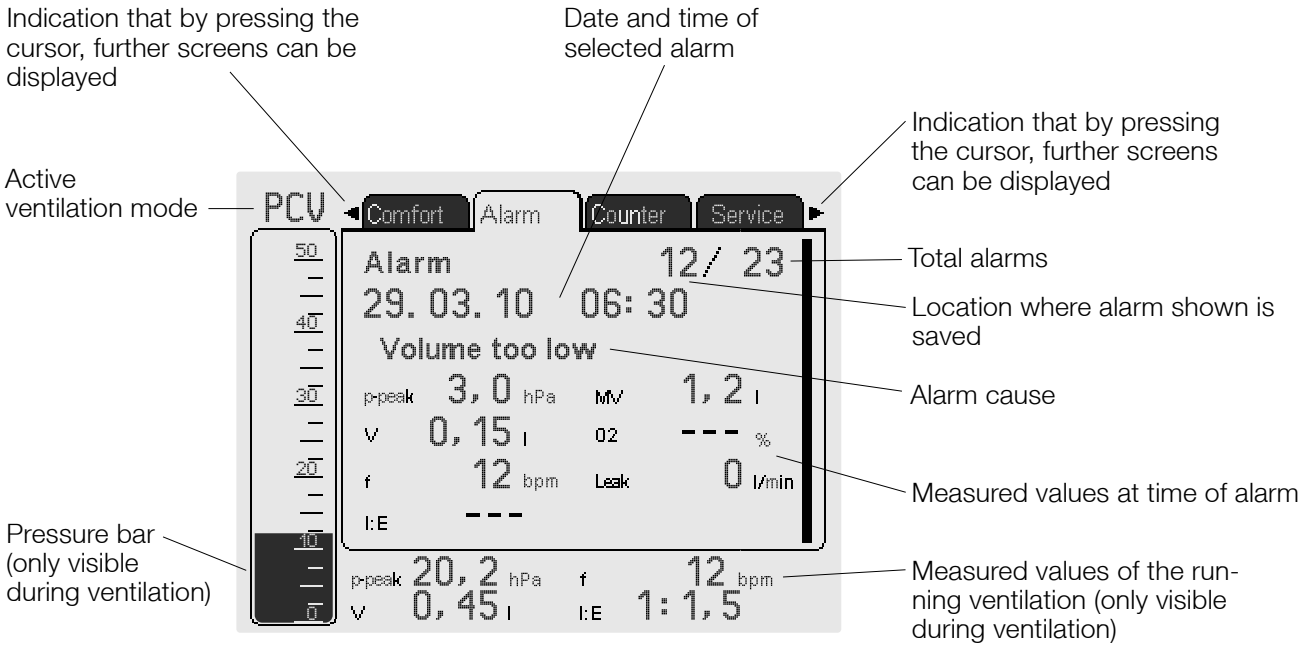


Fig. 38: Alarm screen

THE COUNTER SCREEN

The counter screen contains the running times for ventilation, the device and the blower.

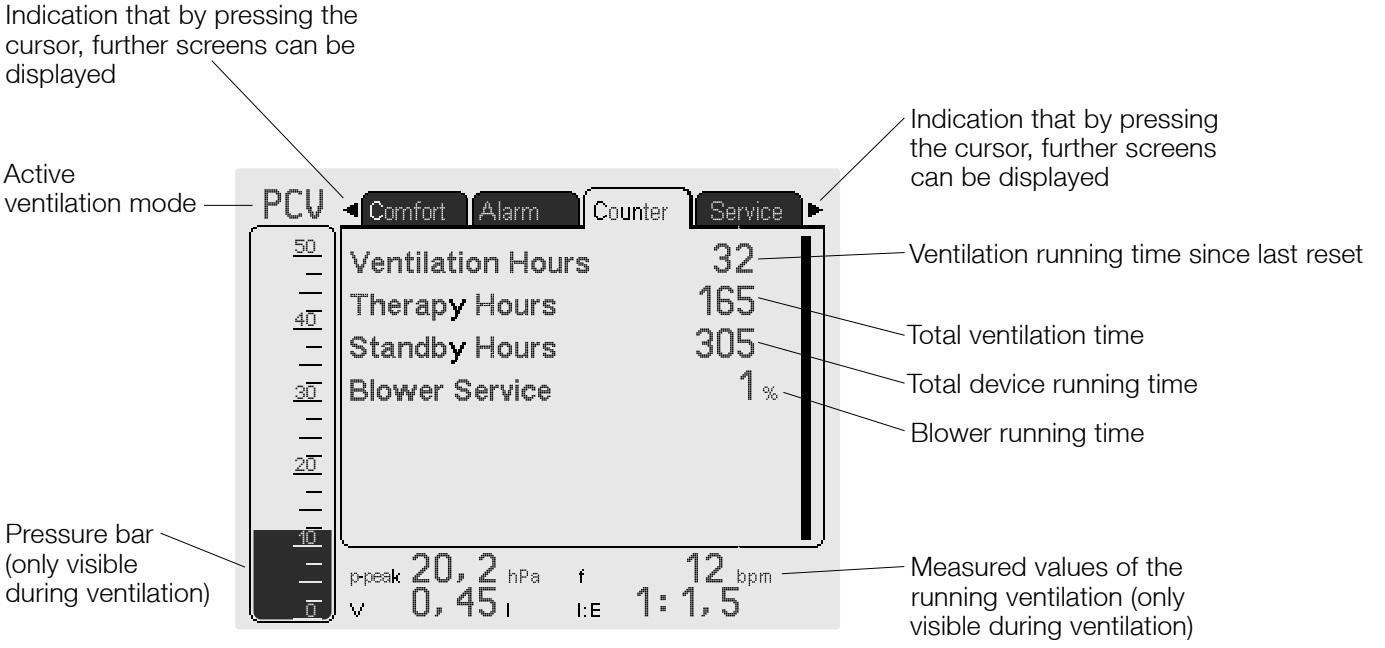


Fig. 39: Counter screen

THE SERVICE SCREEN

Via the service screen you can undertake the manual O_2 sensor calibration (see page 53).

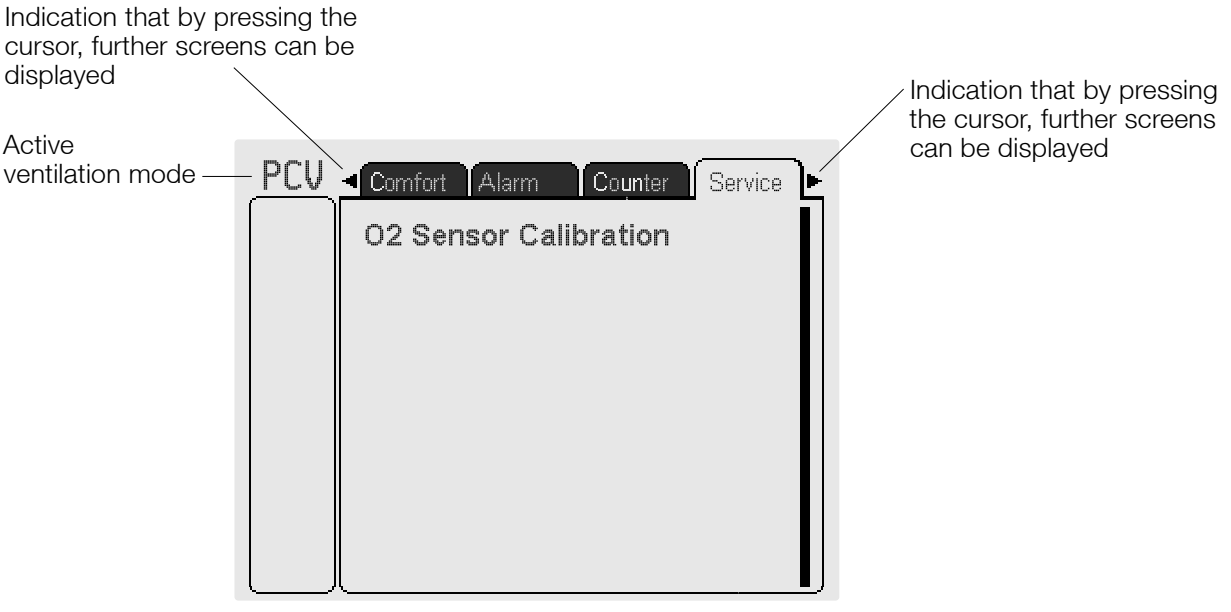


Fig. 40: Service screen

THE STATUS SCREEN

The status screen provides information about:

- the hardware status,
- operating voltage,
- date of last battery test,
- maximum battery capacity,
- the device's serial number and
- the software version.

The parameters in the status screen are purely for information and cannot be changed.

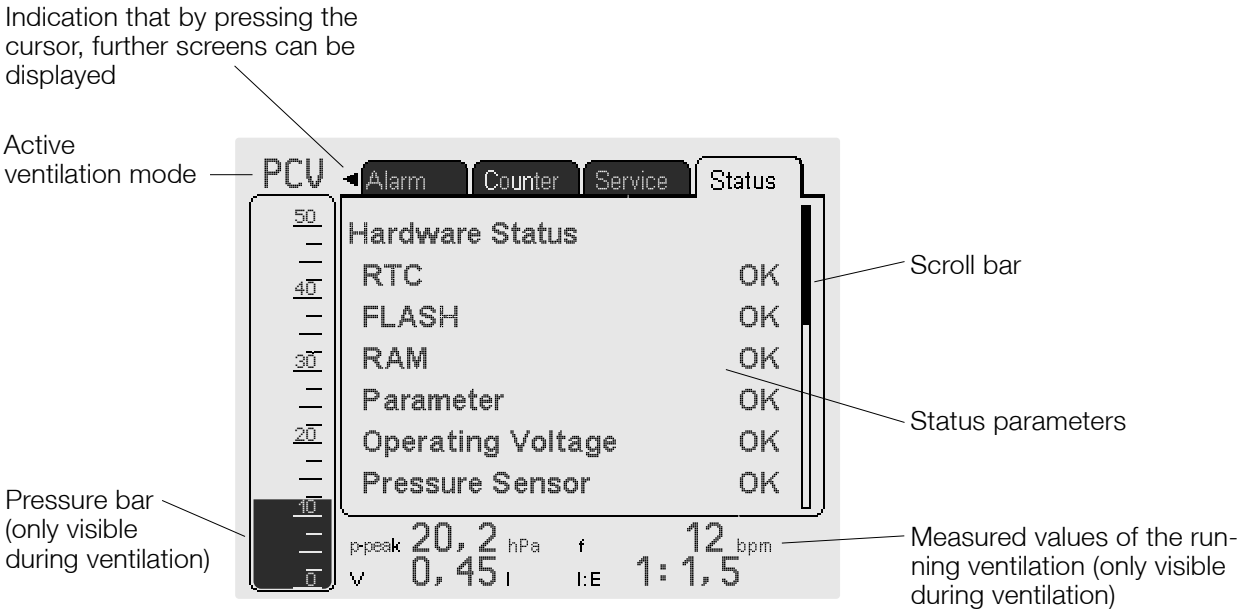


Fig. 41: Counter screen

ALARMS AND ERROR MESSAGES

GENERAL

⚠CAUTION
The alarm limits may only be set by qualified, specialist staff, under the supervision of a physician.

The TRENDvent ventilator has both fixed alarms and adjustable alarms that apply to the respective ventilation mode. All adjustable alarms remain saved when the device is switched off and are active again when it is switched on. All alarms and error messages are displayed visually and/or acoustically. Optionally, medium and high priority alarms can be emitted via a remote alarm.

VISUAL ALARMS

Visual alarms and error messages are displayed

- via the alarm button
- and as highlighted text

Fig. 42: Alarm message “Pressure too low”

Depending on the priority of the alarm, the alarm button flashes as follows:

- Priority HIGH
  10 pulses fast (repeated every 5 seconds);
  red flashes with 2 Hz
- Priority MEDIUM
  3 pulses slow (repeated every 5 seconds);
  yellow flashes with 0.5 Hz
- Priority LOW
  1 pulse; lit yellow

If several alarms are triggered at the same time or in quick succession, the alarm with the highest priority is displayed.

ACOUSTIC ALARMS

Acoustic alarms are emitted by an alarm sound.
As soon as the cause of the alarm disappears, the alarm sound is switched off. The alarm continues to be indicated by the orange light of the alarm button and a text message until it is confirmed by pressing the alarm button.

SUPPRESSING ALARM SOUNDS

The alarm sound can be supressed by pressing the alarm button for 2 minutes. During this time, the alarm sound for any possible further alarms is also suppressed. One exception is the alarm for “Internal Battery empty”, which cannot be muted. The alarm button continues to visually indicate the alarm, even while the alarm sound is suppressed. If the cause of the alarm is not remedied, the alarm sounds again after 2 minutes.
The alarm sound can be suppressed even before the occurrence of an alarm situation by pressing the alarm button; e. g., before briefly disconnecting the tube system from the device for suction. Once the cause of the alarm is remedied, the alarm sound can be reactivated within the 2 minutes by pressing the alarm button again.

IMPORTANT
The alarm for “Internal Battery empty” cannot be muted in battery operation.

ADJUSTABLE ALARMS

The parameters for the alarms shown in Table 10 will be adjusted by the physician.

Alarm parameter/ alarm message	Priority	Cause	Time delay
Pressure Difference / Pressure too high	HIGH	Positive pressure deviation greater than set deviation	15 s or 3 breaths consecutively
Pressure Difference / Pressure too low	HIGH	Negative pressure deviation greater than set deviation	15 s or 3 breaths consecutively
Max. Frequency / Frequency too high	HIGH	Measured frequency greater than “Max. Frequency“	3 breaths consecutively
Apnea	HIGH	Set apnea time exceeded (only with frequency “OFF”)	none
Leakage	HIGH	Leakage greater than set leakage (volume too great for 3 breaths) or flow greater 1 l/s (2 l/s in CPAP mode)	
Max. Volume / Volume too high	HIGH	Tidal volume greater than “Max. Volume”	3 breaths consecutively
Min. Volume / Volume too low	HIGH	Tidal volume smaller than “Min. Volume”	3 breaths consecutively
Max. Oxygen / Oxygen too high	MEDIUM	Measured FiO_2 greater than set “Max. Oxygen”	none
Min. Oxygen / Oxygen too low	MEDIUM	Measured FiO_2 lower than set “Min. Oxygen”	none
Check Expiration Outlet	MEDIUM	In ventilation with valve tube system, no expiration valve present or expiration valve is not open	3 breaths consecutively
Minimum Volume not reached	Note	Tidal volume smaller than set minimum volume - Additional volume insufficient	none

Table 10: Adjustable alarms - alarm messages

ERROR MESSAGES, FIXED ALARMS

HARDWARE ERRORS

Hardware errors are also shown in the status screen.

Error message	Priority	Cause	Remedy
Pressure Sensor	MEDIUM	Offset values of the sensor are outside valid range	Device must be serviced
		Sensor defective or not connected	
Temperature Sensor	MEDIUM	Value of the sensor is outside valid range	Device must be serviced
Flow Sensor	MEDIUM	Sensor defective or not connected	Device must be serviced
Operating Voltage	MEDIUM	Values outside valid ranges (± 5 %, except backup battery)	Device must be serviced
O_2 Sensor	LOW	Offset values of the sensor are outside valid range	Replace oxygen sensor
Calibration data	LOW	Incorrect calibration data	Device must be serviced
RTC	---	Value range infringement in time	Device must be serviced
Flash	---	Error in Flash memory	Device must be serviced
RAM	---	Error in RAM memory	Device must be serviced
Parameter	---	Value range infringement or test number infringement in parameters	Check parameters, as after this message, the default parameters are used; if message occurs frequently, device must be serviced

Table 11: Fixed alarms - software errors

FURTHER ERROR MESSAGES

Error message	Priority	Cause	Remedy
Device Error	HIGH	General error (communication to operating controller interrupted or error detected in motor control)	Device must be serviced
Check Tube System Switch	HIGH	Setting of switch for tube system was changed during ventilation	Move position of setting for tube system on rear of device to correct position
Check Expiration Valve	HIGH	Expiration valve does not allow respiratory air to escape	Check expiration valve and replace if necessary
		Incorrect tube system connected (leakage tube)	Change setting of tube system on rear of device or replace tube system
Incorrect Tube System	HIGH	Incorrect tube system connected (valve tube)	Change setting of tube system on rear of device or replace tube system
Check Measuring Tube	HIGH	Pressure difference to 2nd pressure sensor greater 3 hPa (> 15 s)	Check connection between measuring tube and device
Error Pressure Sensor	HIGH	Offset outside range	Device must be serviced
		Calibration error	
		Pressure constant over long period (> 15 s)	
Error Flow Sensor	HIGH	Pressure constant over long period (> 15 s)	Device must be serviced
Stenosis	HIGH	Measured tidal volume lower than 30 xml	Check tube system
		Flow constant over long period (> 15 s)	
Excess Pressure	HIGH	Pressure greater 60 hPa	Device must be serviced
		Device error → Emergency ventilation	

Error message	Priority	Cause	Remedy
Error O_2 Sensor	MEDIUM	Sensor defective	Exchange or recalibrate oxygen sensor
		Calibration error	
Calibrate O_2 Sensor	LOW	Oxygen sensor plugged in after device was turned on	Calibrate oxygen sensor with ventilation switched off

Table 12: Other alarms - alarm messages

FIXED ALARMS FOR POWER SUPPLY

Error message	Priority	Cause	Remedy
Error Backup Battery	HIGH	Battery block voltage too low	Device must be serviced
Internal Battery empty	HIGH	Battery empty	Battery must be charged; 1 minute until the power supply fails completely; ventilation only possible with external power supply
Error internal Battery	Medium	Battery defective	Device must be serviced
Internal Battery low	MEDIUM	Battery capacity ≤ 10 %	Battery must be charged
Charging of Battery not possible	LOW	Temperature outside specified limits during charging (0 °C ... + 50 °C)	Device must be warmed up or cooled down

Table 13: Fixed alarms for power supply

FURTHER MESSAGES

Message	Priority	Cause
Battery Operation	---	Device was removed from the mains and is now running on internal battery; confirm the message by pressing the alarm button
Safety Mode active	---	Patient not breathing spontaneously; minimum frequency safeguard via the device; only in PSV and ST mode
Switch OFF Ventilation? Yes / No	HIGH	ON/OFF button was pressed or main switch was activated during ventilation, alarm sound is active; to end ventilation, the query must be answered with “Yes”.
ATTENTION! Main Switch OFF	---	Main switch was activated during running ventilation; query whether ventilation should be switched off was confirmed with no; message remains until main switch is switched on again

Table 14: Further messages

SAVING ALARMS

All alarms are saved in the device, including date, alarm time, alarm cause, and the measured values at the time of the alarm. The memory depth is approximately 1 year.

READING OUT THE ALARM MEMORY ON THE DEVICE

You can view the last 200 alarm messages in the alarm screen. To do this, proceed as follows:

1. Activate the alarm screen using the cursors ◀ or ▶.
2. Select “Alarm” using the cursor ▼ or the touch wheel.
3. Press the OK button. The saving location of the alarms and the total number of alarms are highlighted with a black bar.
4. Select the desired alarm using the cursors ▲ or ▼, in order to view the alarm time, alarm cause and measured values at the time of alarm.

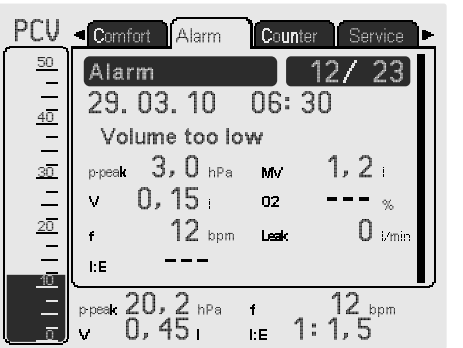


Fig. 43: Reading out alarm memory

FORWARDING ALARMS

Alarms can be forwarded by means of a nurse call or the optionally available remote alarm box. This allows even better monitoring of the device to be achieved in the home or clinic. The use of the remote alarm box or a nurse call is especially recommended when several ventilators are used in one room, as this allows the device generating the alarm to be easily identified.

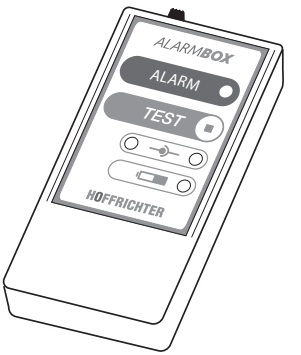


Fig. 44: Remote alarm box

CLEANING AND DISINFECTION

- Before cleaning the device, remove the power plug from the power supply.
- The directions given in this user's manual and the applicable regulations of the hospital or nursing home must be adhered to when hygienically preparing and cleaning the device.
- Standard sterilization methods are not recommended for the device.
- Do not use any aggressive or abrasive cleaning agents (e. g., acetone).
- Do not immerse the device in water or solvents.
- Follow the accessory manufacturer's instructions about cleaning and disinfection.
- Never operate the device without the air filter.
- Only use original HOFFRICHTER filters.

CLEANING THE DEVICE

For cleaning the surface of the device, use a cloth moistened with soapy water. Then, wipe with a cloth moistened with clear water, in order to remove any remains of the soapy water. The device must be completely dry before commissioning.

CLEANING THE COARSE FILTER

The coarse filter must be cleaned once a week. To do this, proceed as follows:

1. Pull the cover of the air inlet from the device, as shown in Fig. 45.
2. Slide the filter cassette out from the cover of the air inlet, as shown in Fig. 46.
3. Remove the coarse filter (black) from the filter cassette.
4. Clean the filter with mild soapy water. Do not use any other agents!
5. Rinse the filter thoroughly with clear water.
6. Let the filter dry completely in the air.

Instead of cleaning the filter, you can insert a new one or replace the entire filter cassette with a new one.

The white fine filter cannot be cleaned. It should be inspected visually weekly and replaced monthly or more frequently if heavily soiled. To do this, proceed as follows:

1. Pull the cover of the air inlet from the device, as shown in Fig. 45.
2. Slide the filter cassette out from the cover of the air inlet, as shown in Fig. 46.
3. Remove the coarse filter (black) from the filter cassette.
4. Remove the fine filter and replace it with a new one.

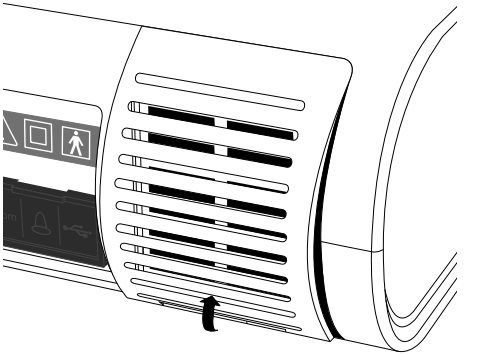


Fig. 45: Pulling out the air inlet cover

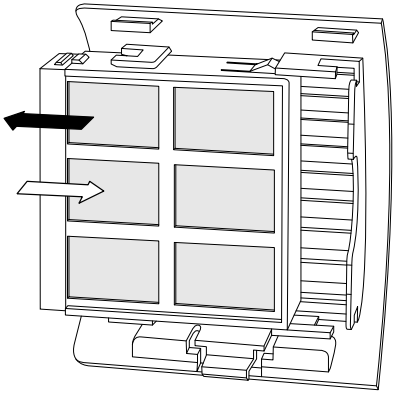


Fig. 46: Sliding out the filter cassette

CLEANING THE MASK

For hygienic reasons, clean the mask every day. To do this, proceed as follows:

1. Disconnect the mask from the tube system.
2. Clean the mask with mild soapy water. Do not use any other agents!
3. Rinse the mask thoroughly with clear water.
4. Let the mask dry completely in the air.

⚠CAUTION
Heavily worn or damaged masks must not be reused and should be disposed of correctly.

CLEANING THE TUBE SYSTEM

⚠CAUTION
A heavily worn or damaged tube system should be disposed of correctly and replaced by a new one.

VALVE TUBE SYSTEM

The tube system supplied is intended for use on one patient only. It must not be cleaned and used for other patients. When using other tube systems, the manufacturer's instructions must be observed.

LEAKAGE TUBE SYSTEM

The tube system supplied is intended for use on one patient only. For reasons of hygiene, clean the leakage tube weekly. To do this, proceed as follows:

1. Disconnect the leakage tube from the mask and the device.
2. Seal the pressure measuring tube on both sides using the plugs, so that no water can penetrate.
3. Clean the leakage tube with mild soapy water. Do not use any other agents!
4. Rinse the leakage tube thoroughly with clear water.
5. Let the leakage tube dry completely in the air.

CLEANING THE OXYGEN SENSOR

When necessary, clean the oxygen sensor with a damp cloth. Before reconnecting the oxygen sensor, leave it to dry completely in the air.

NOTICE
Do not use any cleaning solution and do not sterilize the oxygen sensor.

CLEANING THE HUMIDIFIER

Clean or disinfect the AquaTREND uni humidifier according to the user's manual. When using other humidifiers, the manufacturer's instructions must be observed.

CHANGING THE BACTERIAL FILTER

The bacterial filter must be exchanged according to the manufacturer's stated intervals.

PREPARING THE DEVICE WHEN CHANGING PATIENT

⚠WARNING

Before the device is used on another patient, it must be so comprehensively cleaned and disinfected, that it is free of human pathogens.

If MRSA contamination is suspected, the device must be packaged, with the appropriate labeling, and disinfected accordingly.

IMPORTANT

If the accessories (e.g., tube system, mask, filter, humidifier, etc.) are intended for repeated use, the manufacturer's provisions must be followed.

The hygienic repreparation is described in the service manual and may only carried out by an authorized service agency.

FUNCTIONAL TEST

⚠CAUTION
Until all tests have been passed, the device must not be used and should be checked by an authorized service technician.

The tube system to be used and a test lung (optional accessory) are required for the functional test.

1. Connect the tube system and the test lung to the ventilator.
2. Connect the device to the mains power, as described in the chapter “Power supply” as of page 40.
3. Switch the ventilator on using the main switch on the rear of the device (setting “I”).
4. Start ventilation by pressing the ON/OFF key.

CHECKING THE ACOUSTIC ALARM

Switch the ventilator on using the main switch on the rear of the device (setting “I”). A signal must sound.

CHECKING THE ALARM BUTTON LIGHT

After the device is started, it carries out a self-test of the alarm button. The button must light up in the following order: white > red > yellow > white. The light subsequently goes out.

CHECKING THE DISPLAY

Switch through all screens and check that all display elements are present and legible and that the display’s lighting is functioning. If necessary, check the “Contrast” and “Brightness” settings (see page 70).

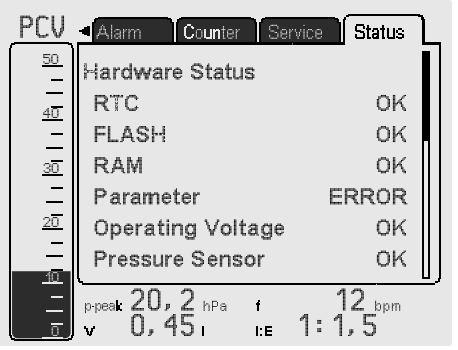


Fig. 47: Status screen with error message

CHECKING THE STATUS SCREEN FOR ERRORS

When the device is started, it carries out a self-test. If any errors are detected, the status screen is automatically displayed (see Fig. 47). Possible errors must first be corrected before the device can be used.

CHECKING THE DATE AND TIME

Switch to the comfort screen and check the date and time. If necessary, correct the setting (see page 65).

CHECKING THE “BATTERY OPERATION” ALARM

Remove the device from the mains power. An alarm must sound and the message “Battery Operation” must appear in the display.

CHECKING THE LEAKAGE ALARM

Remove the test lung from the device. After at most 15 seconds, an alarm must sound and the message “Leakage” must appear in the display.

CHECKING “FREQUENCY TOO HIGH ALARM”

Operate the device in the PSV mode. Set the value of the alarm parameter “Max. Frequency” to lower than the currently measured frequency. Simulate spontaneous respiration, using the test lung, until the alarm sound is triggered and the message “Frequency too high” appears on the display.

MAINTENANCE AND SAFETY-RELATED TEST (SRT)

IMPORTANT
All procedures performed are to be recorded.

To maintain and check the device functions, the device must be subjected to an annual maintenance or safety related test, carried out by an authorized service technician.
The maintenance intervals and all necessary tasks are described, in detail, in the service manual.

DISPOSAL

DEVICE

The device must not be disposed of with the household waste. Please contact the relevant customer services department to find out how to dispose of the device, etc. properly.

Proper disposal saves natural resources and prevents harmful substances being released into the environment.

PACKAGING

The packaging is taken back by the distributor but it can alternatively be disposed of separately with the normal household waste.

OXYGEN SENSOR

The oxygen sensor must not be disposed of with the household waste. Please contact the relevant customer services department to find out how to dispose of the device, etc. properly.

ACCESSORIES

Scope of Delivery	Article number
Functional bag	0001 4875
Power supply (cable approx. 1.80 m)	0001 4510
Mains cable (approx. 1.80 m)	3110 0023
Valve tube system 22 mm (1.80 m)	0000 7967
Leakage tube system with pressure measuring tube and 2 plugs 22 mm (1.80 m)	0000 7116
Filter cassette complete	0000 4880
Coarse filter (pack of 2)	0000 4950
Fine filter (pack of 5)	0000 4951
Oxygen connection adapter, straight	4100 0104
Microfibre cloth	---
User's manual for patients	5000 0397
Patient brief instructions	5000 0405

Optional	Article number
FiO_2 measuring set (oxygen sensor, T adapter, housing gas duct, oxygen sensor connection cable)	0000 4021
Oxygen sensor	2300 0018
T adapter	2300 0019
Housing gas duct	2300 0020
Oxygen sensor connection cable	0000 4115
Oxygen connection adapter, angled	4100 0087
AKKUPACK uni incl. accessories	in preparation
AKKUPACK CARAT incl. accessories	0000 4030
Remote alarm box	0000 4035

TECHNICAL DATA

Power supplies	
Mains operation	100 ... 240 V AC (-20 %, +10 %), 50 ... 60 Hz
DC operation	24 V DC / 5 A
Internal battery operation	Lithium-ion battery, 28.8 V (nominal voltage); 2.25 Ah
External battery operation AKKUPACK CARAT AKKUPACK uni	 25 V (nominal voltage), 7 Ah in preparation
Maximum power consumption	90 W
Electrical protection	Class II, type BF

Comfort parameter settings			
	Factory settings	Settings range	Settings steps
Display brightness	10 %	0 to 100 %	10 %
Display contrast	5	1 to 10	1 Level
Alarm volume		= quiet = medium = loud	---
Softstart	OFF	OFF; 1 to 60 min	1 min
Mask test time	OFF	OFF; 5 to 90 sec	5 sec
Start automatic	OFF	OFF; ON	---
Heating level	3	1 to 5	1 Level

Specifications and performance	
Dimensions (W x D x H)	330 x 280 x 115 mm
Weight	4.2 kg
Max. stable limit pressure	60 hPa
Min. stable limit pressure	0 hPa
Max. working pressure	40 hPa
Min. working pressure	0 hPa
Max. flow	200 l/min

Sound pressure range of audible alarm signal (at 1 m distance)	
Lowest value	> 71 dBA, setting
Medium value	> 75 dBA, setting
Highest value	> 77 dBA, setting

Resistance at 60 l/min	
Inspiratory and expiratory resistance of the device at the patient connection port	Leakage tube system: < 2.6 hPa
	Valve tube system: < 3.4 hPa
Total resistance of the system	< 6 hPa

Operating and transport conditions	
Operating temperature	- 5 °C to + 50 °C
Relative humidity	10 % to 95 %
Air pressure	600 hPa ... 1100 hPa

Storage	
Storage temperature	- 10 °C to + 60 °C
Storage conditions	Store in a dry, vibration-free place, in an upright position; store device and accessories in their original packaging .

Technical requirements for accessories (CE mark required!)	
Oxygen inlet	
Connection type	Quick-connect coupling
Pressure	< 1000 hPa
Flow	< 15 l/min
Bacterial filter	
Connections	22 / 15 mm cone (acc. to EN1281-1)
Resistance	< 2.3 hPa at 60 l/min
Compressible volume	< 66 ml
Internal volume	< 200 ml

CE marking as per EC directive 93/42/EEC.

The manufacturer reserves the right to make technical changes without notice.

MANUFACTURER'S DECLARATION ON ELECTROMAGNETIC COMPATIBILITY

Guidance and manufacturer's declaration – electromagnetic emissions		
The TRENDvent ventilator is intended for use in the electromagnetic environment specified below. The user[1] of the TRENDvent ventilator should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions acc. to CISPR 16-1-2	Group 1	The TRENDvent ventilator uses RF energy only for its internal function. Therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions acc. to CISPR 16-1-2	Class B	The TRENDvent ventilator is suitable for use in all establishments including those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissons acc. to IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions acc. to IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The TRENDvent ventilator is intended for use in the electromagnetic environment specified below. The user [1] of the TRENDvent ventilator should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) acc. to IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst acc. to IEC 61000-4-4	± 2 kV power supply lines ± 1 kV input/output lines	± 2 kV power supply lines ± 1 kV input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge acc. to IEC 61000-4-5	± 1 kV voltage outer conductor - outer conductor ± 2 kV voltage outer conductor - ground	± 1 kV voltage outer conductor - outer conductor ± 2 kV voltage outer conductor - ground	Mains power quality should be that of a typical commercial or hospital environment.

1 Here user is meant in the sense of "Responsible Organization"

Guidance and manufacturer's declaration – electromagnetic immunity			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment – guidance**
Voltage dips, short interruptions and voltage variations on power supply input lines acc. to IEC 61000-4-11	< 5 % U_T (> 95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 s	> 95 % dip in U_T for 0.5 cycle 60 % dip in U_T for 5 cycles 30 % dip in U_T for 25 cycles > 95 % dip in U_T for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the TRENDvent ventilator requires continued operation during power mains interruption, it is recommended that the TRENDvent ventilator is powered from an uninterrupted power supply (UPS) or a battery.
Power frequency (50/60 Hz) magnetic field acc. to IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF acc. to IEC 61000-4-6	3 $V_{\text{effective value}}$ 150 kHz – 80 MHz	3 V	Portable and mobile communications equipment should be used no closer to any part of the TRENDvent ventilator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended safety distance: $d = 1.16 \sqrt{P}$

Guidance and manufacturer's declaration – electromagnetic immunity			
Radiated RF acc. to IEC 61000-4-3	3 V/m 80 MHz – 2.5 GHz	3 V/m	d = 1.16 √P for 800 MHz to 800 MHz d = 2.33 √P for 800 MHz to 2.5 GHz with *P* as the rated maximum output power of the transmitter in watts (W), according to the transmitter's manufacturer, and *d* as the recommended safety distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol.

Note 1 U_T is the mains alternating current before application of the test level.

Note 2 At 80 MHz and 800 MHz the higher frequency range is essential.

Note 3 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a The field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength outside the location in which the TRENDvent ventilator is used exceeds the compliance level, the TRENDvent ventilator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the TRENDvent ventilator.

b Over the frequency range from 150 kHz to 80 MHz the field strength should be lower than 10 V/m.

Recommended separation distances between portable and mobile RF communication equipment and the TRENDvent ventilator

The TRENDvent ventilator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user[1] of the TRENDvent ventilator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the TRENDvent ventilator as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz – 80 MHz $d = 1.16 \sqrt{P}$	**80 MHz – 800 MHz** $d = 1.16 \sqrt{P}$	**800 MHz – 2.5 GHz** $d = 2.33 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.743
1	1.17	1.17	2.3
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1 At 80 MHz and 800 MHz the higher frequency range is essential.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

1 Here user is meant in the sense of “Responsible Organization”

DISCLAIMER

HOFFRICHTER GmbH is not liable for consequences in terms of safety, reliability and performance of the product where:

- interventions, modifications, extensions, calibration, repairs and maintenance are carried out by persons not authorized by us,
- other manufacturers' accessories and spare parts are used that have not been approved by us for use on the product,
- the product is used other than as described in the user's manual or
- the hygiene and cleaning instructions described in the user's manual have not been complied with.

Statutory guarantee rights remain unaffected by this.

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